



Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13


**TENDER DOCUMENT FOR SUPPLY, INSTALLATION,  
COMMISSIONING AND VALIDATION OF VIAL WASHING  
MACHINE WITH DEPYROGENATING TUNNEL AND VIAL  
SEALING MACHINES  
AT HLL BIOTECH LIMITED, CHENGALPATTU**

**13<sup>th</sup> NOVEMBER 2014**

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
Project No : 120310	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	Revision : 00 Date : 2014.11.13

### INDEX

Section No	Contents	Page no
Section I	: Notice inviting Tender (NIT), General Information and Brief Introduction of the Project	4
Section II	: General Instructions to Tenderers (GIT)	11
Section III	: Special Instructions to Tenderers (SIT)	30
Section IV	: General Conditions of Contract (GCC)	31
Section V	: Special Conditions of Contract (SCC)	48
Section VI	: List of Requirements	49
Section VII	: Technical Specifications	50
Section VIII	: Quality Control Requirements	53
Section IX	: Qualification Criteria	54
Section X	: Tender Form	63
Section XI	: Price Schedules	64
Section XII	: Questionnaire	68
Section XIII	: Bank Guarantee Form for EMD	69
Section XIV	: Manufacturer's Authorisation Form	70
Section XV	: Bank Guarantee Form for Advance, Performance Security /AMC Security	71
Section XVI	: Contract Form (A & B)	75
Section XVII	: Proforma of Consignee Receipt Certificate	79
Section XVIII	: Proforma of Final Acceptance Certificate by the Consignee	80
Section XIX	: Check List for the Tenderer	82
Section XX	: Consignee	85
Section XXI	: Integrity Pact	86
Section XXII	: Instruction of Ministry of Shipping & Transport, New Delhi, India	91
Section XXIII	: Schedule of Fiscal Aspects	92

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
Project No : 120310	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	Revision : 00 Date : 2014.11.13

**SECTION I**  
**Notice Inviting Tender (NIT)**  
**HLL Biotech Ltd.**

**INVITES TENDER FOR SUPPLY, INSTALLATION, COMMISSIONING AND VALIDATION OF VIAL  
WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES AT  
HLL BIOTECH LTD, CHENGALPATTU**

Tenders are invited from vendors for Supply, Installation, Commissioning and Validation of following equipments:



SI no	Item (Package)	Equipment ID	Qty (Nos.)	Capacity / Size	EMD	Tender fee
1.	Vial Washing Machine With Depyrogenating Tunnel	F2-VWD 01,	1	200 Vials per minute	Rs. 18,00,000/-	USD 525 or equivalent amount as on tender publishing date
2.	Vial Washing Machine With Depyrogenating Tunnel	F1-VWD 01	1	200 Vials per minute		
3.	Vial Washing Machine With Depyrogenating Tunnel	F1-VWD 02	1	200 Vials per minute		
4.	Vial sealing machine	F2-VSM 01	1	200 Vials per minute		
5.	Vial sealing machine	F1-VSM 01	1	200 Vials per minute		
6.	Vial sealing machine	F1-VSM 02	1	200 Vials per minute		

**Note: The list may vary (increase / decrease) during order finalisation.**

Details regarding important dates are as follows:


SI No.	Description	Schedule
i.	Pre Bid Meeting Date & Time	20-11-2014, at 10:30 HRS
ii.	Pre Bid Meeting Venue	<b>HLL Biotech Limited, Ticel Biopark Campus (Module no. 013-015), CSIR Road, Taramani, Chennai- 600 113</b>
iii.	Closing date & time for receipt of Tender	09-12-2014, at 15:00 Hrs
iv.	Time and date of opening of Technical Bids	09-12-2014 at 15:30 Hrs
v.	Venue of Opening of Techno Commercial Tender	<b>HLL Biotech Limited, Ticel Biopark Campus (Module no. 013-015), CSIR Road, Taramani, Chennai- 600 113</b>

Interested parties may visit [www.lifecarehll.com](http://www.lifecarehll.com) / [www.hllbiotech.com](http://www.hllbiotech.com) & <http://eprocure.gov.in/cppp> to download the Tender. Subsequent amendments/ addendum if any will be published in these websites, The parties are advised to visit the website regularly for updates. Tenders in sealed envelopes superscribing "Tender for Supply, Installation, Commissioning and Validation of vial washing machine with depyrogenating tunnel and vial sealing machines for Integrated Vaccines Complex, Chengalpattu" may be submitted to the address mentioned in Serial no. v of the table above.

Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13



### INSTRUCTIONS TO BIDDERS

1. The successful bidder will have to enter into a written Contract / Agreement with the Purchaser, the terms and conditions of which are enclosed herewith.
2. The tender should be signed in long hand, dated, duly stamped and witnessed at all places provided therein. Also all pages, drawings, corrections/alterations should be initialed/stamped.
3. Bidder must be careful to deliver a bonafide tender. Any tender which proposes any alterations to any of the conditions laid down which proposes any other conditions or any description whatsoever is liable to be rejected.
4. Intimation of tenders' quotation by a telegram/fax will not be considered.
5. Tenders must be accompanied by a certified true copy of the Power of Attorney in favour of the signatory to the tender which interalia should empower him/her to bind the firm to Arbitration Clause given in the Articles of Agreement and Contract conditions.
6. In case a blank tender is being submitted, it should be marked prominently '**BLANK**' on the envelope and signed by the authorized person.
7. In view of postal and other delays, the tenders should be posted sufficiently in advance of the last date fixed for receipt of tenders or be sent by a special messenger. Tender received late shall be liable for rejection.
8. Prices shall be written in ink and shall be entered both in figures and words. In case of discrepancy the figure quoted in words shall be taken as accurate. In case of any discrepancy in the unit and amount, the unit rate shall be taken as accurate.
9. Prices quoted by the bidder shall be firm and valid even if the contract is split in two or more parts among different bidders.

Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

### GENERAL INFORMATION

<b>PROJECT LOCATION</b>	HLL BIOTECH LIMITED, CHENNAI INTEGRATED VACCINES COMPLEX, CHENGALPATTU
<b>PROJECT TITLE</b>	INTEGRATED VACCINES COMPLEX, CHENGALPATTU
<b>CORPORATE OFFICE</b>	<b>HLL Biotech Limited,</b> <b>Ticel Biopark Campus (Module no. 013-015),</b> <b>CSIR Road, Taramani,</b> <b>Chennai- 600 113, Ph no. 044-22544949</b> <b>Email: sureshs@hllbiotech.com,</b> <a href="mailto:ceo@hllbiotech.com">ceo@hllbiotech.com</a> ,
<b>ENGINEERING CONSULTANT</b>	NNE Pharmaplan India Limited  Bangalore Office: # 12, Achiah Shetty Layout R.M.V. Extension Sadashivanagar Bangalore – 560080 Tel.: 080 - 23614415
<b>CLIMATE</b> :	Maximum Temperature: 39.4°C Minimum Temperature: 18.3°C
<b>ACCESS TO SITE</b> :	By Road (Chennai to Chengalpattu GST Road). Nearest Railway Station is Chengalpattu Nearest airport is Chennai

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

## 1. Introduction

HLL Biotech Limited (HBL), a subsidiary of HLL Lifecare Limited, (a CPSU under Ministry of Health & Family Welfare, Government of India, is implementing "an Integrated Vaccines Complex (IVC) - a project of national importance' at Chengalpattu, near Chennai. The proposed complex is a state of the art facility with cGMP compliance for manufacturing vaccines required for the immunization programme of Government of India.



HLL Biotech Limited has associated with NNE Pharmaplan India Limited, hereinafter called as "NP" has been appointed as "Engineering Consultants". NNE Pharmaplan shall design and engineer this facility, incorporating the latest GMP Standards and best practices. This facility shall be built as per the latest International trends and upon completion, shall be in compliance with Indian FDA (Schedule M), WHO/GMP regulations.

One amongst the several other jobs is to supply, install and commission the equipments / systems.

The scope of work involved is detailed in the subsequent paragraphs and is precise to the extent possible. However, it is expected from the supplier to consider and supply all those required for successful installation and functioning of the equipment / system.



## 2. Scope of Vendor

- The scope of vendor would be to comply to the enclosed URS, Plan, supply, execute commission & validate the system as per URS and drawings.
- Quote for the unit against the URS, along with all options. The price to include all spare parts; documentation; packing; freight charges; start-up & commissioning; complete qualification package (FAT, SAT, DQ, IQ, OQ, PQ) and training and charges whatsoever required to complete the task in all respects to ensure the equipment operation is in accordance with the requirements of design documents.
- Involve with the purchaser and the consultants to establish documented evidence that the proposed design of the system is in compliance with the GMP requirements mentioned in the User Requirement Specification, Installation requirement specification and Risk Analysis.
- The complete system should be fabricated and installed as per design review report and the regulations mentioned in the URS (Under point number 2.0) and ultimately allows to validated as per NPI Validation philosophy prepared based on Indian FDA (Schedule M), WHO/GMP regulations
- Quality and Project Planning: The Quality and Project Plan should define the activities to be performed, their timing, who will perform them, the control mechanisms to be used, and the deliverable items. Project Time Schedule must be created for that purpose. This document should define:
  - ✓ Project Milestones
  - ✓ Project Activities
  - ✓ Planned start and end date of each activity
- Quality Assurance activities during manufacturing: E.g. Collecting the material certificates, surface roughness certificates, weld documentation, etc.
- System Build (assembly and system integration): The final assembly of the mechanical, electrical, and control components (hardware and software) into an integrated functional

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

system should be performed by the vendor – according to the design documentation and the approved assembly drawings (e.g. installation drawing, P&ID, electrical diagrams).

- Construction Review: The integrated functional system is reviewed against the design documentation of the component manufacturers and the approved assembly drawings (e.g. installation drawing, P&ID, electrical diagrams). QC inspection and test reports
- Testing: Vendor to describe testing not related to specific user requirements, but which is required for other purposes, e.g. to comply with regulatory requirements applicable to the manufacture of pressure vessels. Details as follows:
  - a) Pressure Vessel Testing: Prior to System Build, the pressure vessel should be subjected for pressure test in accordance with the applicable Pressure Vessel Code.
  - b) Functional Testing: The Functional Testing is not related to specific user requirements, but is required for other purposes, e.g. to comply with regulatory requirements applicable to the manufacture of the system.
  - c) Factory Acceptance Testing: The Factory Acceptance Test is a important milestone. The following tests and inspections will be performed but not limited to:
    1. Inspection to verify that all deliverables are available for shipping
    2. Inspection to verify that the correct system was built
    3. Testing to verify correct operation
  - d) Note: FAT is critical to the delivery on time and equipment performance.
- Installation: Installation is a set of activities that have to be completed before site acceptance testing can start. Such activities include: putting in place, leveling, connecting media (including electrical power), turning on media and checking for leakages, fixing any leakages, checking direction of rotation for electrical motors, calibration, etc. The installation –has to be performed by the vendor.
- Pre-Delivery Inspection and Final Inspection: The Final Inspection should be the last quality related activity performed before delivery to the user site and thus need to be performed after Factory Acceptance Testing.
- **Turnkey (if any): Supply, Installation, Commissioning and Validation of vial washing machine with Depyrogenating tunnel and vial sealing machines.**
- **Project Management: Activities or the procedures to be followed, and responsibilities related to Project Management are as follows:**
  - a) **Project communication:** Biweekly project update should be provided by the vendor in the early stage of this project. while two months before the FAT, Weekly update should be in place .
  - b) **Communication paths:** In general, all communication of the vendor shall be directed through the vendor Project Manager. The vendor Project Manager should forward the information as necessary.
  - c) **Means of communication:** E-mail messages and facsimiles (fax) may be used for communication as alternatives to traditional letters and telephone conversations.


Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00  Date : 2014.11.13</b>

d) **Sanctity of communication:** This also applies to decisions (e.g. approvals, accepted/rejected change requests, etc.), which always shall be communicated in writing. Such e-mail messages or facsimiles are considered equally binding as signed paper documents provided that the following data is provided:

- The full name of the person making the decision
- The date of the decision


- o Progress reporting: See section Project Communication for details on how the progress may be communicated to the user company
- o Documentation Management: Documents need to be trustworthy, reliable, authentic, and available for as long as required by applicable legal, regulatory, or business standards.





Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
Project No : 120310	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	Revision : 00 Date : 2014.11.13

**SECTION - II  
GENERAL INSTRUCTIONS TO TENDERERS (GIT)  
CONTENTS**

SI. No.	Topic
<b>A</b>	<b>PREAMBLE</b>
1	Definitions and Abbreviations
2	Introduction
3	Language of Tender
4	Eligible Tenderers
5	Eligible Goods and Services
6	Tendering Expense & Tender Fee
<b>B</b>	<b>TENDER ENQUIRY DOCUMENTS</b>
7	Contents of Tender Enquiry Documents
8	Amendments to Tender Enquiry Documents
9	Clarification of Tender Enquiry Documents
<b>C</b>	<b>PREPARATION OF TENDERS</b>
10	Documents Comprising the Tender
11	Tender Currencies
12	Tender Prices
13	Indian Agent
14	Firm Price / Variable Price
15	Alternative Tenders
16	Documents Establishing Tenderer's Eligibility and Qualifications
17	Documents Establishing Good's Conformity to Tender Enquiry Document
18	Earnest Money Deposit (EMD)
19	Tender Validity
20	Signing and Sealing of Tender
<b>D</b>	<b>SUBMISSION OF TENDERS</b>
21	Submission of Tenders
22	Late Tender

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

Sl. No.	Topic
23	Alteration and Withdrawal of Tender
<b>E</b>	<b>TENDER OPENING</b>
24	Opening of Tenders
<b>F</b>	<b>SCRUTINY AND EVALUATION OF TENDERS</b>
25	Basic Principle
26	Preliminary Scrutiny of Tenders
27	Minor Infirmary/Irregularity/Non-Conformity
28	Discrepancy in Prices
29	Discrepancy between original and copies of Tender
30	Qualification Criteria
31	Conversion of Tender Currencies to Indian Rupees
32	Schedule-wise Evaluation
33	Comparison of Tenders
34	Additional Factors and Parameters for Evaluation and Ranking of Responsive Tenders
35	Tenderer's capability to perform the contract
36	Contacting the Purchaser
<b>G</b>	<b>AWARD OF CONTRACT</b>
37	Purchaser's Right to Accept any Tender and to Reject any or All Tenders
38	Award Criteria
39	Variation of Quantities at the Time of Award
40	Notification of Award
41	Issue of Contract
42	Non-receipt of Performance Security and Contract by the Purchaser/Consignee
43	Return of EMD
44	Publication of Tender Result
45	Corrupt or Fraudulent Practices
46	Integrity Pact (IP)
47	Paying Authority

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13



## A. PREAMBLE

### 1. Definitions and Abbreviations:

1.1 The following definitions and abbreviations, which have been used in these documents shall have the meanings as indicated below:

### 1.2 Definitions:

- (i) "Purchaser" means the organization and / or its representatives (consultants) purchasing goods and services as incorporated in the Tender Enquiry document.
- (ii) "Tender" means Bids / Quotation / Tender received from a Firm / Tenderer / Bidder.
- (iii) "Tenderer" means Bidder/ the Individual or Firm submitting Bids / Quotation / Tender
- (iii) "Supplier" means the individual or the firm supplying the goods and services as incorporated in the contract.
- (iv) "Goods" means the articles, material, commodities, livestock, furniture, fixtures, raw material, spares, instruments, machinery, equipment, medical equipment, industrial plant etc. which the supplier is required to supply to the purchaser under the contract.
- (v) "Services" means services allied and incidental to the supply of goods, such as transportation, installation, commissioning, provision of technical assistance, training, after sales service, maintenance service and other such obligations of the supplier covered under the contract.
- (vi) "Earnest Money Deposit" (EMD) means Bid Security/ monetary or financial guarantee to be furnished by a tenderer along with its tender.
- (vii) "Contract" means the written agreement entered into between the purchaser and/or consignee and the supplier, together with all the documents mentioned therein and including all attachments, annexure etc. therein.
- (viii) "Performance Security" means monetary or financial guarantee to be furnished by the successful tenderer for due performance of the contract placed on it. Performance Security is also known as Security Deposit.
- (ix) "Consignee" means the organization/person to whom the goods are required to be delivered as specified in the Contract. If the goods are required to be delivered to a person as an interim consignee for the purpose of despatch to another person as provided in the Contract then that "another" person is the consignee, also known as ultimate consignee. Consignee is HBL, Chennai.
- (x) "Specification" means the document/standard that prescribes the requirement with which goods or service has to conform.
- (xi) "Inspection" means activities such as measuring, examining, testing, gauging one or more characteristics of the product or service and comparing the same with the specified requirement to determine conformity.
- (xii) "Day" means calendar day.
- (xiii) "Employer" means HBL, Chennai.



Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

### 1.3 Abbreviations:

- (i) "T E Document" means Tender Enquiry Document
- (ii) "NIT" means Notice Inviting Tenders.
- (iii) "GIT" means General Instructions to Tenderers
- (iv) "SIT" means Special Instructions to Tenderers
- (v) "GCC" means General Conditions of Contract
- (vi) "SCC" means Special Conditions of Contract
- (vii) "DGS&D" means Directorate General of Supplies and Disposals
- (viii) "NSIC" means National Small Industries Corporation
- (ix) "PSU" means Public Sector Undertaking
- (x) "CPSU" means Central Public Sector Undertaking
- (xi) "LSI" means Large Scale Industry
- (xii) "SSI" means Small Scale Industry
- (xiii) "LC" means Letter of Credit
- (xiv) "DP" means Delivery Period
- (xv) "BG" means Bank Guarantee
- (xvi) "ED" means Excise Duty
- (xvii) "CD" means Custom Duty
- (xviii) "VAT" means Value Added Tax
- (xix) "CENVAT" means Central Value Added Tax
- (xx) "CST" means Central Sales Tax
- (xxi) "RR" means Railway Receipt
- (xxii) "BL" means Bill of Lading
- (xxiii) "FOB" means Free on Board
- (xxiv) "FOR" means Free On Rail
- (xxv) "DAP" means Delivered At Place
- (xxvi) "DDP" means Delivery Duty Paid named place of destination (consignee site)
- (xxvii) "INCOTERMS" means International Commercial Terms as on the date of Tender Opening
- (xxviii) "MOH&FW" means Ministry of Health & Family Welfare, Government of India.
- (xxix) "AMC" means Annual maintenance Contract (labour, spare and preventive maintenance)
- (xxx) "RT" means Re-Tender.

## 2. Introduction

- 2.1 The Purchaser has issued these TE documents for purchase of goods and related services as mentioned in subsequent paragraphs which also indicates, inter alia, the required delivery schedule, terms and place of delivery.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

2.2 This section (Section II - "General Instruction Tenderers") provides the relevant information as well as instructions to assist the prospective tenderers in preparation and submission of tenders. It also includes the mode and procedure to be adopted by the purchaser for receipt and opening as well as scrutiny and evaluation of tenders and subsequent placement of contract.

2.3 The tenderers shall also read the Special Instructions to Tenderers (SIT) related to this purchase, as contained in Section III of these documents and follow the same accordingly. Whenever there is a conflict between the GIT and the SIT, the provisions contained in the SIT shall prevail over those in the GIT.

2.4 Before formulating the tender and submitting the same to the purchaser, the tenderer should read and examine all the terms, conditions, instructions, checklist etc. contained in the TE documents. Failure to provide and/or comply with the required information, instructions etc. incorporated in these TE documents may result in rejection of its tender.

### 3. Language of Tender

3.1 The tender submitted by the tenderer and all subsequent correspondence and documents relating to the tender exchanged between the tenderer and the purchaser, shall be written in the English language, unless otherwise specified in the Tender Enquiry. However, the language of any printed literature furnished by the tenderer in connection with its tender may be written in any other language provided the same is accompanied by an English translation and, for purposes of interpretation of the tender, the English translation shall prevail.

3.2 The tender submitted by the tenderer and all subsequent correspondence and documents relating to the tender exchanged between the tenderer and the purchaser, may also be written in the Hindi language, provided that the same are accompanied by English translation, in which case, for purpose of interpretation of the tender etc, the English translations shall prevail.

### 4. Eligible Tenderers



4.1 This invitation for tenders is open to all suppliers who fulfil the eligibility criteria specified against clause 16 of GIT Sec. II in this document.

### 5. Eligible Goods and Services

5.1 All goods and related services to be supplied under the contract shall have their origin in India or any other country with which India has not banned trade relations. The term "origin" used in this clause means the place where the goods are mined, grown, produced, or manufactured or from where the related services are arranged and supplied.

### 6. Tendering Expense and Tender fee

6.1 **Tender Expense:** The tenderer shall bear all costs and expenditure incurred and/or to be incurred by it in connection with its tender including preparation, mailing and submission of its tender and for subsequent processing the same. The purchaser will, in no case be responsible or liable for any such cost, expenditure etc regardless of the conduct or outcome of the tendering process.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

- 6.2 **Tender Cost/Tender fee:** The tenderer should submit the tender fee USD 525 or equivalent amount as on tender publishing date in the form of Demand Draft or Banker's cheque in favour of HLL Biotech limited, payable at Chennai. The DD/ Banker's cheque has to be enclosed along with the technical bid which is non-refundable. In case of cancellation of tender by HBL, the tender cost/fee shall be refunded.

## B. TENDER ENQUIRY DOCUMENTS

### 7. Content of Tender Enquiry Documents



- 7.1 In addition to Section I – "Notice inviting Tender" (NIT), the TE documents include:

- Section II – General Instructions to Tenderers (GIT)
- Section III – Special Instructions to Tenderers (SIT)
- Section IV – General Conditions of Contract (GCC)
- Section V – Special Conditions of Contract (SCC)
- Section VI – List of Requirements
- Section VII – Technical Specifications
- Section VIII – Quality Control Requirements
- Section IX – Qualification Criteria
- Section X – Tender Form
- Section XI – Price Schedules
- Section XII – Questionnaire
- Section XIII – Bank Guarantee Form for EMD
- Section XIV – Manufacturer's Authorisation Form
- Section XV – Bank Guarantee Form for Performance Security/AMC Security
- Section XVI – Contract Forms A & B
- Section XVII – Proforma of Consignee Receipt Certificate
- Section XVIII – Proforma of Final Acceptance Certificate by the consignee
- Section XIX – Check List for the Tenderers
- Section XX – Consignee List
- Section XXI – Integrity Pact
- Section XXII – Instruction of Ministry of Shipping & Transport, New Delhi, India
- Section XXIII – Schedule of Fiscal Aspects

- 7.2 The relevant details of the required goods and services, the terms, conditions and procedure for tendering, tender evaluation, placement of contract, the applicable contract terms and, also, the standard formats to be used for this purpose are incorporated in the above-mentioned documents. The interested tenderers are expected to examine all such details etc to proceed further.

### 8. Amendments to Tender Enquiry documents

- 8.1 At any time prior to the deadline for submission of tenders, the purchaser may, for any reason deemed fit by it, modify the TE documents by issuing suitable amendment(s) to it.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

8.2 Such an amendment will be notified in the website of [www.hllbiotech.com/www.lifecarehll.com/](http://www.hllbiotech.com/www.lifecarehll.com/) <http://eprocure.gov.in/cppp>. The interested parties are advised to regularly visit the website for further updates.

8.3 In order to provide reasonable time to the prospective tenderers to take necessary action in preparing their tenders as per the amendment, the purchaser may, at its discretion extend the deadline for the submission of tenders and other allied time frames, which are linked with that deadline.

### 9. Clarification of Tender Enquiry documents

9.1 A Tenderer requiring any clarification or elucidation on any issue of the TE documents may take up the same during the pre bid conference. The purchaser will respond to such request by publishing the response / clarification in the official websites.

## C. PREPARATION OF TENDERS

### 10. Documents Comprising the Tender



10.1 The Two Bid System, i.e. “**Technical Bid**” and “**Price Bid**” prepared by the tenderer shall comprise the following:

#### A) Technical bid (Un priced Bid)

- i) Earnest money furnished in accordance with GIT clause 18.1 alternatively, documentary evidence as per GIT clause 18.2 for claiming exemption from payment of earnest money.
- ii) Tender Form as per Section X (Un-priced).
- iii) Documentary evidence, as necessary in terms of GIT clauses 4 and 16 establishing that the tenderer is eligible to submit the tender and, also, qualified to perform the contract if its tender is accepted.
- iv) Tenderer/Agent who quotes for goods manufactured by other manufacturer shall furnish Manufacturer’s Authorisation Form.
- v) Power of attorney in favour of the signatory of the tender document.
- vi) Documents and relevant details to establish in accordance with GIT clause 17 that the goods and the allied services to be supplied by the tenderer conform to the requirement of the TE documents.
- vii) Performance Statement as per section IX along with relevant copies of orders and end users’ satisfaction certificate.
- viii) Price Schedule(s) as per Section XI filled up with all the details including Make, Model, etc. of the goods offered with prices blank (without indicating any prices).
- ix) Certificate of country of origin by the bidder from abroad. (Chamber of commerce)
- x) Checklist as per Section XIX.
- xi) IRS and URS (Technical Specification) given as Annexure - I & II, duly filled up and signed and stamped



#### B) Price Bid:

The information given at clause no. 10.1 A) ii) & viii) above should be reproduced with the prices indicated.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

- 10.2 N.B.
1. All pages of the Tender should be page numbered and indexed.
  2. It is the responsibility of tenderer to go through the TE document to ensure furnishing all required documents in addition to above, if any.
- 10.3 The tender should be signed in long hand, dated, duly stamped and witnessed at all places provided therein. Also all pages, drawings, corrections/alterations should be initialled/stamped.
- 10.4 A tender, which does not fulfil any of the above requirements and/or gives evasive information/reply against any such requirement, shall be liable to be ignored and rejected.
- 10.5 Tender sent by fax/telex/cable/electronically shall be ignored.
- 11. Tender currencies**
- 11.1 The tenderer supplying indigenous goods or already imported goods shall quote only in Indian Rupees.
- 11.2 For imported goods if supplied directly from abroad, prices shall be quoted in any freely convertible currencies say US Dollar, Euro, GBP or Yen. As regards price(s) for allied services, if any required with the goods, the same shall be quoted in Indian Rupees only if such services are to be performed /undertaken in India. Commission for Indian Agent, if any and if payable shall be indicated in the space provided for in the price schedule and will be payable in Indian Rupees only. Such conversion of currencies will be done based on rate of exchange declared by the RBI as on the date of 'Price Bid' opening as already incorporated against clause 31 here after.
- 11.3 Tenders, where prices are quoted in any other way shall be treated as non-responsive and rejected.
- 12. Tender Prices**
- 12.1 The Tenderer shall indicate on the Price Schedule provided under Section XI all the specified components of prices shown therein including the unit prices and total tender prices of the goods and services proposes to supply against the requirement. All the columns shown in the price schedule should be filled up as required. If any column does not apply to a tenderer, same should be clarified as "NA" by the tenderer.
- 12.2 The price of the schedule complete in all respect will be evaluated and the L1 party will be identified schedule wise.
- 12.3 The quoted prices for goods offered from within India and that for goods offered from abroad are to be indicated separately in the applicable Price Schedules attached under Section XI.
- 12.4 While filling up the columns of the Price Schedule, the following aspects should be noted for compliance:
- 12.4.1 For domestic goods or goods of foreign origin located within India, the prices in the corresponding price schedule shall be entered separately in the following manner:
- a) The price of the goods, quoted ex-factory/ ex-showroom/ ex-warehouse/ off-the-shelf, as applicable, including all taxes and duties like sales tax, CST VAT, Custom Duty, Excise Duty etc. already paid or payable on the components and raw material used in the



Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

manufacture or assembly of the goods quoted ex-factory etc. or on the previously imported goods of foreign origin quoted ex-showroom etc;

- b) Any sales or other taxes and any duties including excise duty, which will be payable on the goods in India if the contract is awarded;
- c) Charges towards Packing & Forwarding, Inland Transportation Loading/Unloading and other local costs incidental to delivery of the goods to their final destination as specified in the List of Requirements and Price Schedule would be borne by supplier;
- d) The price of Incidental Services, as mentioned in List of Requirements and Price Schedule;
- e) The prices of Turnkey (if any), as mentioned in List of Requirements, Technical Specification and Price Schedule; and
- f) The price of AMC, as mentioned in List of Requirements, Technical Specification and Price Schedule.

12.4.2 For goods offered from abroad, the prices in the corresponding price schedule shall be entered separately in the following manner:

- a) The price of goods quoted DAP at Consignee site basis, as indicated in the List of Requirements and Price Schedule;
- b) The price of goods quoted should be on DAP at Consignee site basis, in India as indicated in the List of Requirements, Price Schedule and Consignee List;
- c) The prices of Turnkey ( if any), as mentioned in List of Requirements, Technical Specification and Price Schedule; and
- d) The price of AMC (Annual Maintenance Contract), as mentioned in List of Requirements, Technical Specification and Price Schedule

12.5 For transportation of imported goods offered from abroad, relevant instructions as incorporated under GCC Clause 10 shall be followed.

12.6 For insurance of goods to be supplied, relevant instructions as provided under GCC Clause 11 shall be followed.



12.7 Unless otherwise specifically indicated in the SCC, the terms FOB & DAP for imported goods offered from abroad, shall be governed by the rules & regulations prescribed in the current edition of INCOTERMS, published by the International Chamber of Commerce, Paris.

12.8 The need for indication of all such price components by the tenderers, as required in this clause (viz., GIT clause 12) is for the purpose of comparison of the tenders by the purchaser and will no way restrict the purchaser's right to award the contract on the selected tenderer on any of the terms offered.

### 13. Indian Agent

13.1 If a foreign tenderer has engaged an agent in India in connection with its tender, the foreign tenderer, in addition to indicating Indian agent's commission, if any, in a manner described under GIT sub clause 11.2 above, shall also furnish the following information:

- a) The complete name and address of the Indian Agent and its permanent income tax account number as allotted by the Indian Income Tax authority.
- b) The details of the services to be rendered by the agent for the subject requirement.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

- c) Details of Service outlets in India, nearest to the consignee(s), to render services during Warranty AMC period.

#### 14. Firm Price

- 14.1 Unless otherwise specified in the SIT, prices quoted by the tenderer shall remain firm and fixed during the currency of the contract and not subject to variation on any account.

#### 15. Alternative Tenders

- 15.1 Alternative Tenders are not permitted.

#### 16. Documents Establishing Tenderers Eligibility and Qualifications



- 16.1 Pursuant to GIT clause 10, the tenderer shall furnish, as part of its tender, relevant details and documents establishing its eligibility to quote and its qualifications to perform the contract if its tender is accepted.

- 16.2 The documentary evidence needed to establish the tenderer's qualifications shall fulfil the following requirements:

- a) In case the tenderer offers to supply goods, which are manufactured by some other firm, the tenderer has been duly authorised by the goods manufacturer to quote for and supply the goods to the purchaser. The tenderer shall submit the manufacturer's authorization letter to this effect as per the standard form provided under Section XIV in this document.
- b) The tenderer has the required financial, technical and production capability necessary to perform the contract and, further, it meets the qualification criteria incorporated in the Section IX in these documents.
- c) In case, the tenderer is not doing business in India, it is duly represented by an agent stationed in India fully equipped and able to carry out the required contractual functions and duties of the supplier including after sale service, maintenance & repair etc. of the goods in question, stocking of spare parts and fast moving components and other obligations, if any, specified in the conditions of contract and/or technical specifications.
- d) In case the tenderer is an Indian agent/authorized representative quoting on behalf of a foreign manufacturer for the **restricted item**, the Indian agent/authorized representative is already enlisted under the Compulsory Enlistment Scheme of Ministry of Finance, Govt. of India, operated through Directorate General of Supplies & Disposals (DGS&D), New Delhi.

#### 17. Documents establishing Good's Conformity to Tender Enquiry document.

- 17.1 The tendered shall provide in its tender the required as well as the relevant documents like technical data, literature, drawings etc. to establish that the goods and services offered in the tender fully conform to the goods and services specified by the purchaser in the TE documents. For this purpose the tendered shall also provide a **clause-by-clause commentary on the technical specifications and other technical details incorporated by the purchaser in the TE Document to establish technical responsiveness of the goods and services offered in its tender.**

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

17.2 In case there is any variation and/or deviation between the goods & services prescribed by the purchaser and that offered by the tenderer, the tenderer shall list out the same in a chart form without ambiguity and provide the same along with its tender.

17.3 If a tenderer furnishes wrong and/or misleading data, statement(s) etc. about technical acceptability of the goods and services offered by it, its tender will be liable to be ignored and rejected in addition to other remedies available to the purchaser in this regard.

**18. Earnest Money Deposit (EMD)**

18.1 Pursuant to GIT clauses 7.1 and 10.1 the tenderer shall furnish along with its tender, earnest money for amount as shown in the NIT). The earnest money is required to protect the purchaser against the risk of the tenderer's unwarranted conduct as amplified under sub-clause 18.7 below.

18.2 The tenderers who are currently registered and, also, will continue to remain registered during the tender validity period with National Small Industries Corporation, New Delhi for the specific goods as per tender enquiry specification shall be eligible for exemption from EMD. Vague stipulations in the Registration Certificates such as "to customers' specification" etc. will not be acceptable for exemption from furnishing of earnest money. In case the tenderer falls in these categories, the tenderer should furnish copy of its valid registration details (with NSIC). The EMD should be furnished in the name of "HLL Biotech Limited, payable at Chennai".

18.3 MSE units who are registered and also will continue to remain registered during the tender validity period with NSIC are exempted from payment of Bid security (EMD) and other benefits as applicable, but authenticated copy of the valid NSIC certificate for tendered item(s) should be submitted along with Technical bid of the Tender to qualify for such exemptions and other benefits.

18.4 The earnest money shall be denominated in Indian Rupees or equivalent currencies as per GIT clause 11.2. The earnest money shall be furnished in one of the following forms:



Account Payee Demand Draft or Bank Guarantee

18.5 The demand draft shall be drawn on any commercial bank in India, in favour of "HLL Biotech Limited" payable at Chennai. If the EMD is in the form of bank guarantee, the same is to be provided from any scheduled commercial bank in India or in the case of foreign tenderer, the same should be routed through a scheduled commercial bank in India as per the format specified under Section XIII of this tender.

18.6 The earnest money shall be valid for a period of forty-five (45) days beyond the validity period of the tender. As validity period of Tender as per Clause 19 of GIT is 120 days, the EMD shall be valid for 165 days from Technical Bid opening date.

18.7 Unsuccessful tenderers' earnest money will be returned to them without any interest, after expiry of the tender validity period, but not later than thirty days after conclusion of the resultant contract. Successful tenderer's earnest money will be returned without any interest, after receipt of performance security from that tenderer.

18.8 Earnest Money is required to protect the purchaser against the risk of the Tenderer's conduct, which would warrant the forfeiture of the EMD. Earnest money of a tenderer will be forfeited, if

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

the tenderer withdraws or amends its tender or impairs or derogates from the tender in any respect within the period of validity of its tender or if it comes to notice that the information/documents furnished in its tender is incorrect, false, misleading or forged without prejudice to other rights of the purchaser. The successful tenderer's earnest money will be forfeited without prejudice to other rights of Purchaser if it fails to furnish the required performance security within the specified period.

18.9 In the case of Bank Guarantee furnished from banks outside India (i.e. foreign Banks), it should be authenticated and countersigned by any nationalised bank or scheduled bank, but not cooperative banks in India by way of back-to-back counter guarantee.

**19. Tender Validity**

19.1 If not mentioned otherwise in the SIT, the tenders shall remain valid for acceptance for a period of 120 days (One hundred and twenty days) from the date of tender opening prescribed in the TE document. Any tender valid for a shorter period shall be treated as unresponsive and rejected.

19.2 In exceptional cases, the tenderers may be requested by the purchaser to extend the validity of their tenders up to a specified period. Such request(s) and responses thereto shall be conveyed by surface mail or by fax/ telex/cable followed by surface mail. The tenderers, who agree to extend the tender validity, are to extend the same without any change or modification of their original tender and they are also to extend the validity period of the EMD accordingly. A tenderer, however, may not agree to extend its tender validity without forfeiting its EMD.

19.3 In case the day up to which the tenders are to remain valid falls on/ subsequently declared a holiday or closed day for the purchaser, the tender validity shall automatically be extended up to the next working day.



**20. Signing and Sealing of Tender**

20.1 The tenderers shall submit their tenders as per the instructions contained in GIT Clause 10

20.2 The tender shall either be typed or written in indelible ink and the same shall be signed by the tenderer or by a person(s) who has been duly authorized to bind the tenderer to the contract. The letter of authorization shall be by a written power of attorney, which shall also be furnished along with the tender.

20.3 The tender shall be duly signed at the appropriate places as indicated in the TE document and all other pages of the tender including printed literature, if any shall be initialled by the same person(s) signing the tender. The tender shall not contain any erasure or overwriting, except as necessary to correct any error made by the tenderer and, if there is any such correction; the same shall be initialled by the person(s) signing the tender.

20.4 The tenderer should seal the tender and write the address of the purchaser and the tender reference number on the envelope. The sentence "NOT TO BE OPENED before (The tenderer is to put the date & time of tender opening)" are to be written on these envelopes. The inner envelopes are then to be put in a bigger outer envelope, which will also be duly sealed, marked etc. as above. If the outer envelope is not sealed and marked properly as above, the purchaser will not assume any responsibility for its misplacement, premature opening, late opening etc.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

- 20.5 The document seeks quotation following **Two Tender System**, in two parts. First part will be known as '**Technical Bid**', and the second part '**Price Bid**' as specified in clause 10 of GIT. Tenderer shall seal 'Technical Bid' and 'Price Bid' separately and covers will be suitably super scribed. Both these sealed covers shall be put in a bigger cover and sealed and procedure prescribed in Paras 20.1 to 20.4 followed.

#### D. SUBMISSION OF TENDERS

##### 21. Submission of Tenders

- 21.1 Unless otherwise specified, the tenders are to be submitted to **The Chief Executive Officer, HLL Biotech Limited, Ticel Biopark Campus (Module no. 013-015), CSIR Road, Taramani, Chennai- 600 113**
- 21.2 The tenderers must ensure that they submit their tenders not later than the closing time and date specified for submission of tenders. It is the responsibility of the tenderer to ensure that their Tenders whether sent by post or by courier or by person, reaches the address mentioned in GIT 21.1 by the specified clearing date and time.
- 21.3 In the event the specified date for submission of tender falls on / is subsequently declared a holiday or closed day for the purchaser, the tenders will be received up to the appointed time on the next working day.

##### 22. Late Tender

- 22.1 A tender, which is received after the specified date and time for receipt of tenders will be treated as "late" tender and will be ignored and not considered.



##### 23. Alteration and Withdrawal of Tender

- 23.1 The tenderer, after submitting its tender, is permitted to alter / modify its tender so long as such alterations / modifications are received duly signed, sealed and marked like the original tender, within the deadline for submission of tenders. Alterations / modifications to tenders received after the prescribed deadline will not be considered.
- 23.2 No tender should be withdrawn after the deadline for submission of tender and before expiry of the tender validity period. If a tenderer withdraws the tender during this period, it will result in forfeiture of the earnest money furnished by the tenderer in its tender.

#### E. TENDER OPENING

##### 24. Opening of Tenders

- 24.1 The purchaser will open the tenders at the specified date and time and at the specified place as indicated in the NIT. In case the specified date of tender opening falls on / is subsequently declared a holiday or closed day for the purchaser, the tenders will be opened at the appointed time and place on the next working day.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

- 24.2 Authorized representatives of the tenderers, who have submitted tenders on time, may attend the tender opening, provided they bring with them letters of authority from the corresponding tenderers.  
The tender opening official(s) will prepare a list of the representatives attending the tender opening. The list will contain the representatives' names & signatures and corresponding tenderers' names and addresses.
- 24.3 Two - Tender system as mentioned in para 20.5 above will be as follows. The Technical Bids are to be opened in the first instance, at the prescribed time and date as indicated in NIT. These Tenders shall be scrutinized and evaluated by the competent committee/ authority with reference to parameters prescribed in the TE document. During the Technical Bid opening, the tender opening official(s) will read the salient features of the tenders like brief description of the goods offered, delivery period, Earnest Money Deposit and any other special features of the tenders, as deemed fit by the tender opening official(s). Thereafter, in the second stage, the Price Bid of only the Technically qualified offers (as decided in the first stage) shall be opened for further scrutiny and evaluation on a date notified after the evaluation of the Technical Bid. The prices, special discount if any of the goods offered etc., as deemed fit by tender opening official(s) will be read out.



## F. SCRUTINY AND EVALUATION OF TENDERS

### 25. Basic Principle

- 25.1 Tenders will be evaluated on the basis of the terms & conditions already incorporated in the TE document, based on which tenders have been received and the terms, conditions etc. mentioned by the tenderers in their tenders. No new condition will be brought in while scrutinizing and evaluating the tenders.

### 26. Preliminary Scrutiny of Tenders

- 26.1 The Purchaser will examine the Tenders to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed stamped and whether the Tenders are generally in order.
- 26.2 Prior to the detailed evaluation of Price Bid, pursuant to GIT Clause 33, the Purchaser will determine the substantial responsiveness of each Tender to the TE Document. For purposes of these clauses, a substantially responsive Tender is one, which conforms to all the terms and conditions of the TE Document without material deviations. Deviations from, or objections or reservations to critical provisions such as those concerning Performance Security (GCC Clause 5), Warranty (GCC Clause 15), EMD (GIT Clause 18), Taxes & Duties (GCC Clause 20), Force Majeure (GCC Clause 26) and Applicable law (GCC Clause 31) will be deemed to be a material deviation. The Purchaser's determination of a Tender's responsiveness is to be based on the contents of the tender itself without recourse to extrinsic evidence.
- 26.3 If a Tender is not substantially responsive (Non-Responsive), it will be rejected by the Purchaser and cannot subsequently be made responsive by the Tenderer by correction of the nonconformity.
- 26.4 The tenders will be scrutinized to determine whether they are complete and meet the essential and important requirements, conditions etc. as prescribed in the TE document. The

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

tenders, which do not meet the basic requirements, are liable to be treated as non – responsive and will be summarily ignored. A non-responsive tender is one which deviates technically or commercially from any specific provision in the tender enquiry.

26.5 The following are some of the important aspects, for which a tender shall be declared non – responsive and will be summarily ignored:

- (i) Tender form as per Section X (signed and stamped) not enclosed
- (ii) Tender is unsigned.
- (iii) Tender validity is shorter than the required period.
- (iv) Required EMD (Amount, validity etc.) / exemption documents have not been provided.
- (v) Tenderer has quoted for goods manufactured by other manufacturer(s) without the required Manufacturer's Authorisation Form as per Section XIV.
- (vi) Tenderer has not agreed to give the required performance security.
- (vii) Goods offered are not meeting the tender enquiry specification.
- (viii) Tenderer has not agreed to other essential condition(s) specially incorporated in the tender enquiry like terms of payment, liquidated damages clause, warranty clause, dispute resolution mechanism applicable law.
- (ix) Poor/ unsatisfactory past performance.
- (x) Tenderers who stand deregistered/banned/blacklisted by any Govt. Authorities.
- (xi) Tenderer is not eligible as per GIT Clauses 4.1 & 16.1.
- (xii) Tenderer has not quoted for the entire quantity as specified in the List of Requirements in the quoted schedule.
- (xiii) The signed Integrity Pact not enclosed by the Tenderer.
- (xiv) IRS and URS given in Annexure-I, II & III, not duly filled, signed and stamped.

## 27. Minor Infirmity /Irregularity/Non-Conformity



27.1 If during the preliminary examination, the purchaser find any minor informality and/or irregularity and/or non-conformity in a tender, the purchaser may waive the same provided it does not constitute any material deviation and financial impact and, also, does not prejudice or affect the ranking order of the tenderers. Wherever necessary, the purchaser will convey its observation on such 'minor' issues to the tenderer, asking the tenderer to respond by a specified date. If the tenderer does not reply by the specified date or gives evasive reply without clarifying the point at issue in clear terms, that tender will be liable to be ignored.

## 28. Discrepancies in Prices

28.1 If, in the price structure quoted by a tenderer, there is discrepancy between the unit price and the total price (which is obtained by multiplying the unit price by the quantity), the unit price shall prevail and the total price corrected accordingly, unless the purchaser feels that the tenderer has made a mistake in placing the decimal point in the unit price, in which case the total price as quoted shall prevail over the unit price and the unit price corrected accordingly.

28.2 If there is an error in a total price, which has been worked out through addition and/or subtraction of subtotals, the subtotals shall prevail and the total shall be corrected accordingly; and

28.3 If there is a discrepancy between the amount expressed in words and figures, the amount in words shall prevail, subject to sub clause 28.1 and 28.2 above.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

28.4 If, as per the judgement of the purchaser, there is any such arithmetical discrepancy in a tender, the same will be suitably conveyed to the tenderer by registered / speed post. If the tenderer does not agree to the observation of the purchaser, the tender is liable to be ignored.

**29. Discrepancy between original and copies of Tender**

29.1 In case, any discrepancy is observed between the text etc. of the original copy and that in the other copies of the same tender set, the text etc. of the original copy shall prevail. Here also, the purchaser will convey its observation suitably to the tenderer by register / speed post and, if the tenderer does not accept the purchaser's observation, that tender will be liable to be ignored.

**30. Qualification Criteria**

30.1 Tenders of the tenderers, who do not meet the required Qualification Criteria prescribed in Section IX, will be treated as non - responsive and will not be considered further.

**31. Conversion of tender currencies to Indian Rupees**

31.1 In case the TE document permits the tenderers to quote their prices in different currencies, all such quoted prices of the responsive tenderers will be converted to a single currency viz., Indian Rupees for the purpose of equitable comparison and evaluation, as per the exchange rates established by the Reserve Bank of India for similar transactions, as on the date of 'Price bid' opening.

**32. Schedule/ Package -wise Evaluation**

32.1 In case the List of Requirements contains more than one schedule/ Package, the responsive tenders will be evaluated and compared separately for each schedule/package. The tender for a schedule/ package will not be considered if the complete requirements prescribed in that schedule/ package are not included in the tender. However, as already mentioned in GIT sub clause 12.2, the tenderers have the option to quote for any one or more schedules/ package.

**33. Comparison of Tenders**

33.1 Unless mentioned otherwise in Section – III – Special Instructions to Tenderers and Section – VI – List of Requirements, the comparison of the responsive tenders shall be carried out on Delivery Duty Paid (DDP) consignee site basis. The quoted turnkey (if any) prices and AMC prices will also be added for comparison/ranking purpose for evaluation.

**34. Additional Factors and Parameters for Evaluation and Ranking of Responsive Tenders**



34.1 DELETED

34.2 The purchaser's evaluation of tender will also take into account the additional factors, if any, incorporated in SIT in the manner and to the extent indicated therein.

34.3 The Purchaser reserves the right to give the price preference to small-scale sectors etc. and purchase preference to central public sector undertakings as per the instruction in vogue while evaluating, comparing and ranking the responsive tenders.

**35. Tenderer's capability to perform the contract**



Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

35.1 The purchaser, through the above process of tender scrutiny and tender evaluation will determine to its satisfaction whether the tenderer, whose tender has been determined as the lowest evaluated responsive tender is eligible, qualified and capable in all respects to perform the contract satisfactorily. If, there is more than one schedule/ package in the List of Requirements, then, such determination will be made separately for each schedule/ package.

35.2 The above-mentioned determinations will, inter alia, take into account the tenderer's financial, technical and production capabilities for satisfying all the requirements of the purchaser as incorporated in the TE document. Such determination will be based upon scrutiny and examination of all relevant data and details submitted by the tenderer in its tender as well as such other allied information as deemed appropriate by the purchaser.

### **36. Contacting the Purchaser**

36.1 From the time of submission of tender to the time of awarding the contract, if a tenderer needs to contact the purchaser for any reason relating to this tender enquiry and / or its tender, it should do so only in writing.

36.2 In case a tenderer attempts to influence the purchaser in the purchaser's decision on scrutiny, comparison & evaluation of tenders and awarding the contract, the tender of the tenderer shall be liable for rejection in addition to appropriate administrative actions being taken against that tenderer, as deemed fit by the purchaser.

## **G. AWARD OF CONTRACT**

### **37. Purchaser's Right to accept any tender and to reject any or all tenders**

37.1 The purchaser reserves the right to accept in part or in full any tender or reject any or more tender(s) without assigning any reason or to cancel the tendering process and reject all tenders at any time prior to award of contract, without incurring any liability, whatsoever to the affected tenderer or tenderers.

### **38. Award Criteria**



38.1 Subject to GIT clause 37 above, the contract will be awarded to the lowest evaluated responsive tenderer decided by the purchaser in terms of GIT Clause 35.

### **39. Variation of Quantities at the Time of Award/ Currency of Contract**

39.1 At the time of awarding the contract, the purchaser reserves the right to increase or decrease by up to fifty (50) per cent, the quantity of goods and services mentioned in the schedule (s) in the "List of Requirements" (rounded off to next whole number) without any change in the unit price and other terms & conditions quoted by the tenderer.

39.2 If the quantity has not been increased at the time of the awarding the contract, the purchaser reserves the right to increase by up to fifty (50) per cent, the quantity of goods and services mentioned in the contract (rounded off to next whole number) without any change in the unit price and other terms & conditions mentioned in the contract, during the currency of the contract after one year from the Date of Notification of Award.

### **40. Notification of Award**

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

40.1 Before expiry of the tender validity period, the purchaser will notify the successful tenderer(s) in writing, by registered / speed post/ courier or by fax/telex/cable (to be confirmed by registered / speed post/courier) that its tender for goods & services, which have been selected by the purchaser, has been accepted, also briefly indicating therein the essential details like description, specification and quantity of the goods & services and corresponding prices accepted. The successful tenderer must furnish to the purchaser the required performance security within thirty days from the date of dispatch of this notification, failing which the EMD will be forfeited and the award will be cancelled. Relevant details about the performance security have been provided under GCC Clause 5 under Section IV.

40.2 The Notification of Award shall constitute the conclusion of the Contract.

**41. Issue of Contract**

41.1 Promptly after notification of award, the Purchaser/Consignee will mail the contract form (as per Section XVI) duly completed and signed, in duplicate, to the successful tenderer by registered / speed post/courier.

41.2 Within twenty one days from the date of the contract, the successful tenderer shall return the original copy of the contract, duly signed and dated, to the Purchaser by registered / speed post/courier.

41.3 The Purchaser- reserves the right to issue the Notification of Award consignee wise.

**42. Non-receipt of Performance Security and Contract by the Purchaser/Consignee**

42.1 Failure of the successful tenderer in providing performance security and / or returning contract copy duly signed in terms of GIT clauses 40 and 41 above shall make the tenderer liable for forfeiture of its EMD and, also, for further actions by the Purchaser/Consignee against it as per the clause 24 of GCC – Termination of default.

**43. Return of E M D**

43.1 The earnest money of the successful tenderer and the unsuccessful tenderers will be returned to them without any interest, whatsoever, in terms of GIT Clause 18.7

**44. Publication of Tender Result**



44.1 The name and address of the successful tenderer(s) receiving the contract(s) will be mentioned in the notice board/bulletin/web site of the purchaser.

**45. Corrupt or Fraudulent Practices**

45.1 It is required by all concerned namely the Consignee/Tenderers/Suppliers etc to observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the Purchaser: -

(a) defines, for the purposes of this provision, the terms set forth below as follows:

(i) “corrupt practice” means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution; and

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

- (ii) “fraudulent practice” means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Purchaser, and includes collusive practice among Tenderers (prior to or after Tender submission) designed to establish Tender prices at artificial non-competitive levels and to deprive the Purchaser of the benefits of free and open competition;
- (b) will reject a proposal for award if it determines that the Tenderer recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question;
- (c) will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a contract by the purchaser if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing the contract.

#### 46. Integrity Pact (IP)

The Integrity Pact (IP) will be one of the conditions in this tender enquiry. It will be considered to be a material deviation resulting into ignoring and rejecting the tender if the tenderers do not agree to accept it. The detailed terms of the IP are given below:

##### The Public Authority commits that:

- No official will demand or accept any illicit gratification to give any of the parties an advantage at any stage of the project.
- All necessary and appropriate technical, legal and administrative information related to the contract will be made public
- None of the officials will make available confidential information to a bidder/contractor to give unfair advantage in the contract
- Declaration by all concerned officials any conflict of interest and disclosure of own and family assets
- Officials will report to appropriate government authority about any breach/attempt to breach a commitment.


##### The Bidder commits that:

- they will not offer any illicit gratification to obtain unfair advantage
- they will not collude with other parties to impair transparency and fairness
- they will not accept any advantage in exchange for unprofessional behavior
- will disclose all payments made to agents and intermediaries
- it will demonstrate existence of organization-wide code of conduct forbidding unethical practices

##### Penalties:



For failure to implement IP, officials will be subject to penal action and bidders will face cancellation of contract, forfeiture of bond, liquidated damages and blacklisting. Action will not require criminal conviction but be based on “no-contest” after the evidence is made available or there can be no material doubts. Disputes in IP implementation would be resolved by arbitration detailed in IP.

**Integrity Pact has to be signed and submitted by the Tenderer along with the filled up Tenders, failing which the Tender is liable to be rejected. Integrity Pact is enclosed in Section-XXI**

Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	nne pharmaplan®
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00  Date : 2014.11.13</b>

**47. Paying Authority:**

- 47.1 The payment for the supplies of stores / goods / equipments which including agency commission, turnkey (if any), installation and commissioning and any other payment mentioned in the tender enquiry will be made by **“HLL Biotech Limited”**.


Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

**SECTION - III  
SPECIAL INSTRUCTIONS TO TENDERERS (SIT)**

Sl. No.	GIT Clause No.	Topic	SIT Provision
A	1 to 6	Preamble	No Change
B	7 to 9	TE documents	No Change
C	10 to 20	Preparation of Tenders	No Change
D	21 to 23	Submission of Tenders	No Change
E	24	Tender Opening	No Change
F	25 to 33, 35,36	Scrutiny and Evaluation of Tenders	No Change
G	37 to 47	Award of Contract	No Change



In case of any conflict between the provision in the GIT and that in the SIT, the provision contained in the SIT shall prevail.

**34. The tenderer shall necessarily quote for all the items of the relevant Price Schedules (Section XI A to XI D) of the Tender, failing which the Purchaser reserves the right to disqualify and reject the tenderer.**

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**SECTION - IV  
GENERAL CONDITIONS OF CONTRACT (GCC)  
TABLE OF CLAUSES**

<b>SI No.</b>	<b>Topic</b>
1	Application
2	Use of contract documents and information
3	Patent Rights
4	Country of Origin
5	Performance Security
6	Technical Specifications and Standards
7	Packing and Marking
8	Inspection, Testing and Quality Control
9	Terms of Delivery
10	Transportation of Goods
11	Insurance
12	Spare parts
13	Incidental services
14	Distribution of Dispatch Documents for Clearance/Receipt of Goods
15	Warranty
16	Assignment
17	Sub Contracts
18	Modification of contract
19	Prices
20	Taxes and Duties
21	Terms and mode of Payment
22	Delay in the supplier's performance
23	Liquidated Damages
24	Termination for default
25	Termination for insolvency
26	Force Majeure
27	Termination for convenience
28	Governing language
29	Notices
30	Resolution of disputes
31	Applicable Law
32	General/Miscellaneous Clauses

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**SECTION - IV  
GENERAL CONDITIONS OF CONTRACT (GCC)**

**1. Application**

- 1.1 The General Conditions of Contract incorporated in this section shall be applicable for this purchase to the extent the same are not superseded by the Special Conditions of Contract prescribed under Section V, List of requirements under Section VI and Technical Specification under Section VII of this document.

**2. Use of contract documents and information**



- 2.1 The supplier shall not, without the purchaser's prior written consent, disclose the contract or any provision thereof including any specification, drawing, sample or any information furnished by or on behalf of the purchaser in connection therewith, to any person other than the person(s) employed by the supplier in the performance of the contract emanating from this TE document. Further, any such disclosure to any such employed person shall be made in confidence and only so far as necessary for the purposes of such performance for this contract.
- 2.2 Further, the supplier shall not, without the purchaser's prior written consent, make use of any document or information mentioned in GCC sub-clause 2.1 above except for the sole purpose of performing this contract.
- 2.3 Except the contract issued to the supplier, each and every other document mentioned in GCC sub-clause 2.1 above shall remain the property of the purchaser and, if advised by the purchaser, all copies of all such documents shall be returned to the purchaser on completion of the supplier's performance and obligations under this contract.

**3. Patent Rights**

- 3.1 The supplier shall, at all times, indemnify and keep indemnified the purchaser, free of cost, against all claims which may arise in respect of goods & services to be provided by the supplier under the contract for infringement of any intellectual property rights or any other right protected by patent, registration of designs or trademarks. In the event of any such claim in respect of alleged breach of patent, registered designs, trademarks etc. being made against the purchaser, the purchaser shall notify the supplier of the same and the supplier shall, at his own expenses take care of the same for settlement without any liability to the purchaser.

**4. Country of Origin**

- 4.1 All goods and services to be supplied and provided for the contract shall have the origin in India or in the countries with which the Government of India has trade relations.
- 4.2 The word "origin" incorporated in this clause means the place from where the goods are mined, cultivated, grown, manufactured, produced or processed or from where the services are arranged.
- 4.3 The country of origin may be specified in the Price Schedule

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

## 5. Performance Security

- 5.1 Within ten (10) days from date of the issue of notification of award by the Purchaser/Consignee, the supplier, shall furnish performance security to the Purchaser/Consignee for an amount equal to five percent (5%) of the total value of the contract, valid up to sixty (60) days after the date of completion of all contractual obligations by the supplier, including the warranty obligations, initially valid for a period of minimum 23 months from the date of Notification of Award
- 5.2 The Performance security shall be denominated in Indian Rupees or in the currency of the contract as detailed below:
- a) It shall be in the form of Bank Guarantee issued by a Scheduled Commercial bank in India or in the case of a foreign tenderer, the same shall be routed through a Nationalised Indian Bank, in the prescribed form as provided in section XV of this document in favour of the Purchaser. The validity of the Fixed Deposit receipt or Bank Guarantee will be for a period up to sixty (60) days beyond Warranty Period.
- 5.3 In the event of any failure /default of the supplier with or without any quantifiable loss to the government including furnishing of Bank Guarantee for AMC security as per Proforma in Section XV, the amount of the performance security is liable to be forfeited.
- 5.4 In the event of any amendment issued to the contract, the supplier shall, within twenty-one (21) days of issue of the amendment, furnish the corresponding amendment to the Performance Security (as necessary), rendering the same valid in all respects in terms of the contract, as amended.
- 5.5 The supplier shall enter into Annual Maintenance Contract as per the 'Contract Form – B' in Section XVI with the Consignee/Purchaser, 3 (three) months prior to the completion of Warranty Period. The AMC will commence from the date of expiry of the Warranty Period.
- 5.6 Subject to GCC sub – clause 5.3 above, the Purchaser/Consignee will release the Performance Security without any interest to the supplier on completion of the supplier's all contractual obligations including the warranty obligations & after receipt of Consignee wise (in the case of more than one consignee) bank guarantee for AMC security in favour of the consignee as per the format in Section XV.



## 6. Technical Specifications and Standards

- 6.1 The Goods & Services to be provided by the supplier under this contract shall conform to the technical specifications and quality control parameters mentioned in 'Technical Specification'; 'Quality Control Requirements' under Sections VII and Section VIII of this document and URS enclosed as annexure to this document.

## 7. Packing and Marking

- 7.1 The packing for the goods to be provided by the supplier should be strong and durable enough to withstand, without limitation, the entire journey during transit including transshipment (if any), rough handling, open storage etc. without any damage, deterioration etc. As and if necessary, the size, weights and volumes of the packing cases shall also take into consideration, the remoteness of the final destination of the goods and availability or



Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

otherwise of transport and handling facilities at all points during transit up to final destination as per the contract.

7.2 The quality of packing, the manner of marking within & outside the packages and provision of accompanying documentation shall strictly comply with the requirements as provided in Technical Specifications and Quality Control Requirements under Sections VII and VIII and in SCC under Section V. In case the packing requirements are amended due to issue of any amendment to the contract, the same shall also be taken care of by the supplier accordingly.

7.3 Packing instructions:

Unless otherwise mentioned in the Technical Specification and Quality Control Requirements under Sections VII and Section VIII and in SCC under Section V, the supplier shall make separate packages for each consignee (in case there is more than one consignee mentioned in the contract) and mark each package on three sides with the following with indelible paint of proper quality:

- a. contract number and date
- b. brief description of goods including quantity
- c. packing list reference number
- d. country of origin of goods
- e. consignee's name and full address and
- f. supplier's name and address



## **8. Inspection, Testing and Quality Control**

8.1 The purchaser and/or its nominated representative(s) will, without any extra cost to the purchaser, inspect and/or test (FAT) the ordered goods and the related services to confirm their conformity to the contract specifications and other quality control details incorporated in the contract. The purchaser shall inform the supplier in advance, in writing, the purchaser's programme for such inspection (FAT) and, also the identity of the officials to be deputed for this purpose. The cost towards the transportation, boarding & lodging will be borne by the purchaser and/or its nominated representative(s).

8.2 The Technical Specification and Quality Control Requirements incorporated in the contract / URS shall specify what inspections and tests are to be carried out and, also, where and how they are to be conducted. If such inspections and tests are conducted in the premises of the supplier or its subcontractor(s), all reasonable facilities and assistance, including access to relevant drawings, design details and production data, shall be furnished by the supplier to the purchaser's inspector at no charge to the purchaser.

8.3 If during such inspections (FAT) and tests the contracted goods fail to conform to the required specifications and standards, the purchaser's inspector may reject them and the supplier shall either replace the rejected goods or make all alterations necessary to meet the specifications and standards, as required, free of cost to the purchaser and resubmit the same for conducting the inspections and tests again.

8.4 In case the contract stipulates pre-despatch inspection of the ordered goods at supplier's premises, the supplier shall put up the goods for such inspection to the purchaser's inspector well ahead of the contractual delivery period, so that the purchaser's inspector is able to complete the inspection within the contractual delivery period.

Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00  Date : 2014.11.13</b>

8.5 If the supplier tenders the goods to the purchaser's inspector for inspection at the last moment without providing reasonable time to the inspector for completing the inspection within the contractual delivery period, the inspector may carry out the inspection and complete the formality beyond the contractual delivery period at the risk and expense of the supplier. The fact that the goods have been inspected after the contractual delivery period will not have the effect of keeping the contract alive and this will be without any prejudice to the legal rights and remedies available to the purchaser under the terms & conditions of the contract.

8.6 The purchaser's/consignee's contractual right to inspect, test and, if necessary, reject the goods after the goods' arrival at the final destination shall have no bearing of the fact that the goods have previously been inspected and cleared by purchaser's inspector during pre-despatch inspection mentioned above.

8.7 Goods accepted by the purchaser/consignee and/or its inspector at initial inspection and in final inspection in terms of the contract shall in no way dilute purchaser's/consignee's right to reject the same later, if found deficient in terms of the warranty clause of the contract, as incorporated under GCC Clause 15.

8.8 If stipulated by the Purchaser, the Principal/ Foreign or Domestic suppliers shall also have the equipment inspected by recognised/ reputed agency like SGS, Lloyd or equivalent (acceptable to the purchaser) prior to despatch at the supplier's cost and furnish necessary certificate from the said agency in support of their claim.

**9. Terms of Delivery**

9.1 Goods shall be delivered by the supplier in accordance with the terms of delivery specified in the **Schedule of Fiscal Aspects**.

**10. Transportation of Goods**

10.1 Instructions for transportation of imported goods offered from abroad:



The supplier shall not make part-shipments and/or transshipment without the express/prior written consent of the purchaser. The supplier is required under the contract to deliver the goods under DAP at consignee site basis.

10.2 Transportation of domestic goods including goods already imported by the supplier to be done by the supplier himself and the goods to be delivered at the site of the consignee at his own cost.

**11. Insurance:**

11.1 Unless otherwise instructed in the SCC, the supplier shall make arrangements for insuring the goods against loss or damage incidental to manufacture or acquisition, transportation, storage and delivery in the following manner:

I. In case of supply of domestic goods on consignee site basis, the supplier shall be responsible till the entire stores contracted for arrival in good condition at destination. The transit risk in this respect shall be covered by the Supplier by getting the stores duly insured. The insurance cover shall be obtained by the Supplier and should be valid till 3 months after the receipt of goods by the consignee.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

II. In case of supply of the imported goods on CIP Named port of Destination Basis, the additional extended Insurance (local transportation and storage) would be borne by the Supplier from the port of entry to the consignee site for a period including 3 months beyond date of delivery.

- 11.2 If the equipment is not commissioned and handed over to the consignee within 3 months, the insurance will be extended by the supplier at their own cost till the successful installation, testing, commissioning, qualification and handing over of the goods to the consignee. In case the delay in the installation and commissioning is due to handing over of the site to the supplier by the consignee, such extensions of the insurance will still be done by the supplier, but the insurance extension charges at actuals will be reimbursed..

## 12. Spare parts

- 12.1 If specified in the List of Requirements and in the resultant contract, the supplier shall supply/provide any or all of the following materials, information etc. pertaining to spare parts manufactured and/or supplied by the supplier:

- a) The spare parts as selected by the Purchaser/Consignee to be purchased from the supplier, subject to the condition that such purchase of the spare parts shall not relieve the supplier of any contractual obligation including warranty obligations; and
- b) In case the production of the spare parts is discontinued:
  - i. Sufficient advance notice to the Purchaser/Consignee before such discontinuation to provide adequate time to the purchaser to purchase the required spare parts etc., and
  - ii. Immediately following such discontinuation, providing the Purchaser/Consignee, free of cost, the designs, drawings, layouts and specifications of the spare parts, as and if requested by the Purchaser/Consignee.

- 12.2 Supplier shall carry sufficient inventories to assure ex-stock supply of consumable spares for the goods so that the same are supplied to the Purchaser/Consignee promptly on receipt of order from the Purchaser/Consignee.



## 13. Incidental services

- 13.1 Subject to the stipulation, if any, in the SCC (Section – V), List of Requirements (Section – VI) and the Technical Specification (Section – VII), the supplier shall be required to perform the following services.

- i. Installation & commissioning, Supervision and Demonstration of the goods
- ii. Providing required jigs and tools for assembly, minor civil works required for the Completion of the installation.
- iii. Training of Consignee for operating and maintaining the goods
- iv. Supplying required number of operation & maintenance manual for the goods

## 14. Distribution of Dispatch Documents for Clearance/Receipt of Goods

The supplier shall send all the relevant despatch documents well in time to the Purchaser / Consignee to enable the Purchaser/Consignee clear or receive (as the case may be) the goods in terms of the contract.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

Unless otherwise specified in the SCC, the usual documents involved and the drill to be followed in general for this purpose are as follows.

- A) For Domestic Goods, including goods already imported by the supplier under its own arrangement

Within 24 hours of despatch, the supplier shall notify the purchaser, consignee, and others concerned if mentioned in the contract, the complete details of despatch and also supply the following documents to them by registered post / speed post (or as instructed in the contract):

- (i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;
- (ii) Two copies of packing list identifying contents of each package;
- (iii) Inspection certificate issued by the nominated Inspection agency, if any.
- (iv) Certificate of origin;
- (v) Manufacturers/Supplier's warranty certificate & In-house inspection certificate.



- B) For goods imported from abroad

Within 24 hours of despatch, the supplier shall notify the purchaser, consignee, and others concerned if mentioned in the contract, the complete details of despatch and also supply the following documents to them by registered post / speed post (or as instructed in the contract).

- (i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;
- (ii) Original and four copies of the negotiable clean, on-board Bill of Lading/Airway bill, marked freight pre-paid and four copies of non-negotiable Bill of Lading/Airway bill;
- (iii) Four Copies of packing list identifying contents of each package;
- (iv) Manufacturer's/Supplier's warranty certificate
- (v) Certificate of origin
- (vi) Port of Loading;
- (vii) Port of Discharge and
- (viii) Expected date of arrival.



## 15. Warranty

- 15.1 The supplier warrants comprehensively that the goods supplied under the contract is new, unused and incorporate all recent improvements in design and materials unless prescribed otherwise by the purchaser in the contract. The supplier further warrants that the goods supplied under the contract shall have no defect arising from design, materials (except when the design adopted and / or the material used are as per the Purchaser's/Consignee's specifications) or workmanship or from any act or omission of the supplier, that may develop under normal use of the supplied goods under the conditions prevailing in India.
- 15.2 This warranty shall remain valid for 1 (one) year after the goods or any portion thereof as the case may be, have been delivered to the final destination and installed and commissioned at the final destination and accepted by the Purchaser/Consignee in terms of the contract, unless specified otherwise in the SCC.

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

- a. No conditional warranty like mishandling, manufacturing defects etc. will be acceptable.
  - b. Warranty as well as Annual Maintenance Contract will be inclusive of all accessories and Turnkey (if any) work and it will also cover all wearable & non wearable components.
  - c. Replacement and repair will be under taken for the defective goods.
  - d. Proper marking has to be made for all spares for identification like printing of installation and repair dates.
- 15.3 In case of any claim arising out of this warranty, the Purchaser/Consignee shall promptly notify the same in writing to the supplier. The period of the warranty will be as per G.C.C clause number 15.2 above irrespective of any other period mentioned elsewhere in the bidding documents.
- 15.4 Upon receipt of such notice, the supplier shall, within 24 hours on a 24(hrs) X 7 (days) X 365 (days) basis respond to take action and to repair or replace the defective goods or parts thereof, free of cost, at the ultimate destination within 48 hours. The supplier shall take over the replaced parts/goods after providing their replacements and no claim, whatsoever shall lie on the purchaser for such replaced parts/goods thereafter. The penalty clause for non-rectification will be applicable as per tender conditions.
- 15.5 In the event of any rectification of a defect or replacement of any defective goods during the warranty period, the warranty for the rectified/replaced goods shall be extended to a further period of twelve (12) months from the date such rectified / replaced goods starts functioning to the satisfaction of the purchaser.
- 15.6 If the supplier, having been notified, fails to respond to take action to repair or replace the defect(s) within 24 hours on a 24(hrs) X 7 (days) X 365 (days) basis, the purchaser may proceed to take such remedial action(s) as deemed fit by the purchaser, at the risk and expense of the supplier and without prejudice to other contractual rights and remedies, which the purchaser may have against the supplier.
- 15.7 During Warranty period, the supplier is required to visit consignee's site at least once in 3 months commencing from the date of the installation for preventive maintenance of the goods.
- 15.8 The Purchaser/Consignee reserve the rights to enter into Annual Maintenance Contract with the Supplier for the period as mentioned in Section VII, Technical Specifications after the completion of warranty period.
- 15.9 The supplier along with its Indian Agent and the AMC provider shall ensure continued supply of the spare parts for the machines and equipments supplied by them to the purchaser for 10 years from the date of installation and handing over.
- 15.10 The Supplier along with its Indian Agent and the AMC Provider shall always accord most favoured purchaser status vis-à-vis its other /Purchasers of its equipments/machines/goods etc. and shall always give the most competitive price for its machines/equipments supplied to the Purchaser/Consignee.

## 16. Assignment

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

16.1 The Supplier shall not assign, either in whole or in part, its contractual duties, responsibilities and obligations to perform the contract, except with the Purchaser's prior written permission.

**17. Sub Contracts**

17.1 The Supplier shall notify the Purchaser in writing of all sub contracts awarded under the contract if not already specified in its tender. Such notification, in its original tender or later, shall not relieve the Supplier from any of its liability or obligation under the terms and conditions of the contract.

17.2 Sub contract shall be only for bought out items and sub-assemblies.

17.3 Sub contracts shall also comply with the provisions of GCC Clause 4 ("Country of Origin").

**18. Modification of contract**

18.1 If necessary, the purchaser may, by a written order given to the supplier at any time during the currency of the contract, amend the contract by making alterations and modifications within the general scope of contract in any one or more of the following:

- a) Specifications, drawings, designs etc. where goods to be supplied under the contract are to be specially manufactured for the purchaser,
- b) Mode of packing,
- c) Incidental services to be provided by the supplier
- d) Mode of despatch,
- e) Place of delivery, and
- f) Any other area(s) of the contract, as felt necessary by the purchaser depending on the merits of the case.



18.2 In the event of any such modification/alteration causing increase or decrease in the cost of goods and services to be supplied and provided, or in the time required by the supplier to perform any obligation under the contract, an equitable adjustment shall be made in the contract price and/or contract delivery schedule, as the case may be, and the contract amended accordingly. If the supplier doesn't agree to the adjustment made by the Purchaser/Consignee, the supplier shall convey its views to the Purchaser/Consignee within twenty-one days from the date of the supplier's receipt of the Purchaser's/Consignee's amendment / modification of the contract.

**19. Prices**

19.1 Prices to be charged by the supplier for supply of goods and provision of services in terms of the contract shall not vary from the corresponding prices quoted by the supplier in its tender.

**20. Taxes and Duties**

20.1 A) The total composite price shall comprise of unit price and all other components of price need to be individually indicated quoted against the goods/material/service, it proposes to provide under the contract in the following manner:

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

- 20.2 I. The Basic unit price (Ex-Factory Price) of the goods/services/materials, Excise Duty, Sales Tax, Freight, Forwarding, Packing, service tax, insurance and any other levies/charges already paid or payable by the contractor/supplier shall be quoted separately.
- 20.3 II. The liability to pay all taxes, levies etc., shall be of contractor and HBL will not entertain any claim whatsoever in this respect.
- 20.4 B) No concessional form except Sales Tax form 'C' for the items as specified in the schedule and meant for use in HBL, shall be provided by HBL. Form 'C' shall be provided by HBL only on the specific request of the supplier.
- 20.5 For the purpose of evaluation of financial Bid, composite price inclusive of all taxes and levies will be considered.
- 20.6 The unit wise price break up is necessary for the purpose of information and verification of composite price so quoted by the supplier.
- 20.7 The supplier shall submit to HBL documents/proof of payment of all taxes/levies along with exemption certificate if any, to avail applicable benefits by HBL.

## 21. Terms and Mode of Payment

### 21.1 Payment Terms

Payment shall be made subject to recoveries, if any, by way of liquidated damages or any other charges as per terms & conditions of contract in the following manner.

#### A) Payment for Domestic Goods Or Foreign Origin Located Within India.

Payment shall be made in Indian Rupees as specified in the contract in the following manner:

##### a) Advance



An advance of 10% of the contract value shall be released against Bank guarantee equivalent to 110% of the advance amount and submission of 5 % of the contract value as Security Deposit/ Performance Security in the form of Bank Guarantee from any scheduled commercial bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.

##### b) The 90% of payment shall be made within 15 days from the date submission of all the required documents and invoice as per the schedule given below.

##### On delivery at site:

**70 % of the contract price shall be paid on receipt of goods in good condition and upon the submission of the following documents:**

- (i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;
- (ii) Consignee Receipt Certificate as per Section XVII in original issued by the authorized representative of the consignee;
- (iii) Two copies of packing list identifying contents of each package;
- (iv) Dispatch Clearance from Purchaser or authorized agent
- (v) Inspection certificate issued by the nominated Inspection agency, if any.
- (vi) Certificate of Country of origin.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

- c) On Installation Qualification (IQ) & Submission of IQ report by purchaser  
5% of the contract Value
- d) On Operational Qualification (OQ) & submission of OQ report by purchaser  
5% of the Contract Value
- e) **On validation and Final Acceptance Certificate by Purchaser:**

Balance 10 % payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.

**B) Payment for Imported Goods:**

Payment against Imported goods shall be made in the currency through irrevocable, non-transferable Letter of Credit (LC) opened in favour of the supplier in a bank in his country as specified in the contract in the following manner:

**a) Advance**

10% of the net DAP price after submission of Bank guarantee equivalent to 110% of the advance amount in the same currency along with submission of Security Deposit / Performance security equal to 5% of the contract value in the form of a bank guarantee from or in the case of a foreign tenderer, the same shall be endorsed by a Nationalized Indian Bank. The advance bank guarantee shall be valid for a period upto the completion of the contract.



**b) The 90% of payment shall be made through irrevocable, non-transferable Letter of Credit (LC) opened in favour of the supplier in a bank in his country on submission of all the required documents and invoice as per the schedule given below.**

**On Receipt of Goods at site:**



70% of the net DAP price (DAP price less Indian Agency commission) of the goods delivered shall be paid and upon submission of documents specified hereunder:

- (i) Four copies of supplier's invoice showing contract number, goods description, quantity, unit price and total amount;
  - (ii) Original and four copies of the negotiable clean, on-board Bill of Lading/ Airway bill , marked freight pre-paid and four copies of non-negotiable Bill of Lading/Airway bill;
  - (iii) Four Copies of packing list identifying contents of each package;
  - (iv) Documents also to be submitted for payment of LC confirming that dispatch documents has already been sent to all concerned as per the contract within 24 hours;
  - (v) Manufacturer's/Supplier's warranty certificate;
  - (vi) Manufacturer's own factory inspection report and
  - (vii) Certificate of origin by the chamber of commerce of the concerned country;
  - (viii) Goods receipt certificate by the ultimate consignee on receipt of goods at this site/warehouse as per section XVII of this tender document.
- c) On Installation Qualification (IQ) & Submission of IQ report by purchaser  
5% of the net DAP price



Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	Revision : 00 Date : 2014.11.13

- d) On Operational Qualification (OQ) & submission of OQ report by purchaser  
5% of the net DAP price
- e) **On validation and Final Acceptance Certificate by Purchaser:**  
Balance 10 % of the net DAP price payment would be made against 'Final Acceptance Certificate' as per the proforma mentioned in Section XVIII of this tender document to be issued by the consignee/ purchaser subject to recoveries, if any, either on account of non-rectification of defects/deficiencies not attended by the Supplier or otherwise.
- f) Payment of incidental services (including installation & commissioning, supervision, demonstration and training) will be paid in Indian Rupees to the Manufacturer's Authorized Indian representative or to the principal in their currency.
- g) **Payment of customs clearance and handling charges, loading/ unloading, inland transportation, incidental costs till consignee site** will be paid in Indian Rupees to the Manufacturer's Authorized Indian representative or to the principal in their currency on intimation to the purchaser with Bill of Entry and supporting documents. However Customs duty will be paid in Indian Rupees to the customs department directly by HBL on intimation by the vendor's Customs Clearing Agent with demand notice / Assessment order from Customs
- h) **Payment of Indian Agency Commission:**  
  
Indian Agency commission will be paid to the manufacturer's agent in Indian rupees indicated in the relevant Price Schedule (as per prevailing rate of exchange ruling on the date of Contract) and shall not be subject to further escalation / exchange variation. 100% Payment shall be paid in Indian Rupees to the Indian Agent after 100 % payment to the foreign principal.
- i) **Payment for services:**  
In case of separate service order issued to the vendor, the payment terms shall be as below:
- a) 50% of service order value against installation
  - b) 30% of service order value against commissioning
  - c) Balance 20% of service order value against Final Acceptance Certificate by Purchaser
- C) **Payment of Turnkey (if any) (For Supply, Installation, Commissioning and Validation of vial washing machine with Depyrogenating tunnel and vial sealing machines):**  
Turnkey (if any) payment will be made to the manufacturer's agent in Indian rupees indicated in the relevant Price Schedule.
- Payment of Turnkey (if any) shall be made in the following stages:
- d) 50% against installation
  - e) 30% against commissioning
  - f) Balance 20% against Final Acceptance Certificate by Purchaser.
- D) **Payment for Annual Maintenance Contract Charges:**  
The Consignee/Purchaser will enter into AMC with the supplier at the rates as stipulated in the contract, three months prior to completion of warranty period. The payment of AMC will be

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

made on half yearly basis after satisfactory completion of said period, duly certified by the consignee.



However entering into an agreement on AMC with the Supplier on completion of warranty period is the sole discretion of the Purchaser

- 21.2 The supplier shall not claim any interest on payments under the contract.
- 21.3 Where there is a statutory requirement for tax deduction at source, such deduction towards income tax and other tax as applicable will be made from the bills payable to the Supplier at rates as notified from time to time.
- 21.4 Irrevocable & non – transferable LC shall be opened by the Purchaser. However, if the supplier requests specifically to open confirmed LC, the extra charges would be borne by the supplier. If LC is required to be extended and/or amended for reasons not attributable to the purchaser/consignee, the charges thereof shall be borne by the supplier.
- 21.5 The payment shall be made in the currency / currencies authorised in the contract.
- 21.6 The supplier shall send its claim for payment in writing, when contractually due, along with relevant documents etc., duly signed with date, to the purchaser.
- 21.7 While claiming payment, the supplier has also to certify in the bill that the payment being claimed is strictly in terms of the contract and all the obligations on the part of the supplier for claiming that payment has been fulfilled as required under the contract.
- 21.8 In case where the supplier is not in a position to submit its bill for the balance payment for want of receipted copies of Inspection Note from the consignee and the consignee has not complained about the non-receipt, shortage, or defects in the supplies made, balance amount will be paid by the paying authority without consignee's receipt certificate after three months from the date of the preceding part payment for the goods in question, subject to the following conditions:
- (a) The supplier will make good any defect or deficiency that the consignee (s) may report within six months from the date of despatch of goods.
  - (b) Delay in supplies, if any, has been regularized.
  - (c) The contract price where it is subject to variation has been finalized.
  - (d) The supplier furnishes the following undertakings:

"I/We, \_\_\_\_\_ certify that I/We have not received back the Inspection Note duly receipted by the consignee or any communication from the purchaser or the consignee about non-receipt, shortage or defects in the goods supplied. I/We \_\_\_\_\_ agree to make good any defect or deficiency that the consignee may report within three months from the date of receipt of this balance payment.

## 22. Delay in the supplier's performance



- 22.1 The supplier shall deliver of the goods and perform the services under the contract within the time schedule specified by the Purchaser/Consignee in the List of Requirements and as incorporated in the contract.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

- 22.2 Subject to the provision under GCC clause 26, any unexcused delay by the supplier in maintaining its contractual obligations towards delivery of goods and performance of services shall render the supplier liable to any or all of the following sanctions:
- (i) Imposition of liquidated damages,
  - (ii) Forfeiture of its performance security and
  - (iii) Termination of the contract for default.
- 22.3 If at any time during the currency of the contract, the supplier encounters conditions hindering timely delivery of the goods and performance of services, the supplier shall promptly inform the Purchaser/Consignee in writing about the same and its likely duration and make a request to the Purchaser/Consignee for extension of the delivery schedule accordingly. On receiving the supplier's communication, the Purchaser/Consignee shall examine the situation as soon as possible and, at its discretion, may agree to extend the delivery schedule, with or without liquidated damages for completion of supplier's contractual obligations by issuing an amendment to the contract.
- 22.4 When the period of delivery is extended due to unexcused delay by the supplier, the amendment letter extending the delivery period shall, inter alia contain the following conditions:
- a. The Purchaser/Consignee shall recover from the supplier, under the provisions of the clause 23 of the General Conditions of Contract, liquidated damages on the goods and services, which the Supplier has failed to deliver within the delivery period stipulated in the contract.
  - b. That no increase in price on account of any ground, whatsoever, including any stipulation in the contract for increase in price on any other ground and, also including statutory increase in or fresh imposition of customs duty, excise duty, sales tax/ VAT, Service Tax and Works Contract Tax or on account of any other tax or duty which may be levied in respect of the goods and services specified in the contract, which takes place after the date of delivery stipulated in the contract shall be admissible on such of the said goods and services as are delivered and performed after the date of the delivery stipulated in the contract.
  - c. But nevertheless, the Purchaser/Consignee shall be entitled to the benefit of any decrease in price on account of reduction in or remission of customs duty, excise duty, sales tax/ VAT, Service Tax and Works Contract Tax or any other duty or tax or levy or on account of any other grounds, which takes place after the expiry of the date of delivery stipulated in the contract.
- 22.5 The supplier shall not dispatch the goods after expiry of the delivery period. The supplier is required to apply to the Purchaser/Consignee for extension of delivery period and obtain the same before despatch. In case the supplier dispatches the goods without obtaining an extension, it would be doing so at its own risk and no claim for payment for such supply and / or any other expense related to such supply shall lie against the purchaser.

### **23. Liquidated damages**

- 23.1 Subject to GCC clause 26, if the supplier fails to deliver any or all of the goods or fails to perform the services within the time frame(s) incorporated in the contract, the Purchaser/Consignee shall, without prejudice to other rights and remedies available to the Purchaser/Consignee under the contract, deduct from the contract price, as liquidated damages, a sum equivalent to 0.5% (Zero point Five percent) per week of delay or part thereof on delayed supply of goods and/or services until actual delivery or performance

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

subject to a maximum of 5% (Five percent) of the contract value. Once the maximum is reached Purchaser/Consignee may consider termination of the contract as per GCC 24.

During the above-mentioned delayed period of supply and / or performance, the conditions incorporated under GCC sub-clause 22.4 above shall also apply.

#### **24. Termination for default**

24.1 The Purchaser/Consignee , without prejudice to any other contractual rights and remedies available to it (the Purchaser/Consignee ), may, by written notice of default sent to the supplier, terminate the contract in whole or in part, if the supplier fails to deliver any or all of the goods or fails to perform any other contractual obligation(s) within the time period specified in the contract, or within any extension thereof granted by the Purchaser/Consignee pursuant to GCC sub-clauses 22.3 and 22.4.

24.2 In the event of the Purchaser/Consignee terminates the contract in whole or in part, pursuant to GCC sub-clause 24.1 above, the Purchaser/Consignee may procure goods and/or services similar to those cancelled, with such terms and conditions and in such manner as it deems fit and the supplier shall be liable to the Purchaser/Consignee for the extra expenditure, if any, incurred by the Purchaser/Consignee for arranging such procurement.

24.3 Unless otherwise instructed by the Purchaser/Consignee, the supplier shall continue to perform the contract to the extent not terminated.

#### **25. Termination for insolvency**



25.1 If the supplier becomes bankrupt or otherwise insolvent, the purchaser reserves the right to terminate the contract at any time, by serving written notice to the supplier without any compensation, whatsoever, to the supplier, subject to further condition that such termination will not prejudice or affect the rights and remedies which have accrued and / or will accrue thereafter to the Purchaser/Consignee.

#### **26. Force Majeure**

26.1 Notwithstanding the provisions contained in GCC clauses 22, 23 and 24, the supplier shall not be liable for imposition of any such sanction so long the delay and/or failure of the supplier in fulfilling its obligations under the contract is the result of an event of Force Majeure.

26.2 For purposes of this clause, Force Majeure means an event beyond the control of the supplier and not involving the supplier's fault or negligence and which is not foreseeable and not brought about at the instance of , the party claiming to be affected by such event and which has caused the non – performance or delay in performance. Such events may include, but are not restricted to, acts of the Purchaser/Consignee either in its sovereign or contractual capacity, wars or revolutions, hostility, acts of public enemy, civil commotion, sabotage, fires, floods, explosions, epidemics, quarantine restrictions, strikes excluding by its employees , lockouts excluding by its management, and freight embargoes.

26.3 If a Force Majeure situation arises, the supplier shall promptly notify the Purchaser/Consignee in writing of such conditions and the cause thereof within twenty one days of occurrence of such event. Unless otherwise directed by the Purchaser/Consignee in writing, the supplier shall continue to perform its obligations under the contract as far as reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

26.4 If the performance in whole or in part or any obligation under this contract is prevented or delayed by any reason of Force Majeure for a period exceeding sixty days, either party may at its option terminate the contract without any financial repercussion on either side.

26.5 In case due to a Force Majeure event the Purchaser/Consignee is unable to fulfil its contractual commitment and responsibility, the Purchaser/Consignee will notify the supplier accordingly and subsequent actions taken on similar lines described in above sub-paragraphs.

**27. Termination for convenience**

27.1 The Purchaser/Consignee reserves the right to terminate the contract, in whole or in part for its (Purchaser's/Consignee's) convenience, by serving written notice on the supplier at any time during the currency of the contract. The notice shall specify that the termination is for the convenience of the Purchaser/Consignee. The notice shall also indicate interalia, the extent to which the supplier's performance under the contract is terminated, and the date with effect from which such termination will become effective.

27.2 The goods and services that are complete and ready in terms of the contract for delivery and performance within thirty days after the supplier's receipt of the notice of termination shall be accepted by the Purchaser/Consignee following the contract terms, conditions and prices. For the remaining goods and services, the Purchaser/Consignee may decide:

- a) To get any portion of the balance completed and delivered at the contract terms, conditions and prices; and / or
- b) To cancel the remaining portion of the goods and services and compensate the supplier by paying an agreed amount for the cost incurred by the supplier towards the remaining portion of the goods and services.

**28. Governing language**

28.1 The contract shall be written in English language following the provision as contained in GIT clause 3. All correspondence and other documents pertaining to the contract, which the parties exchange, shall also be written accordingly in that language.

**29. Notices**



29.1 Notice, if any, relating to the contract given by one party to the other, shall be sent in writing or by cable or telex or facsimile and confirmed in writing. The procedure will also provide the sender of the notice, the proof of receipt of the notice by the receiver. The addresses of the parties for exchanging such notices will be the addresses as incorporated in the contract.

29.2 The effective date of a notice shall be either the date when delivered to the recipient or the effective date specifically mentioned in the notice, whichever is later.

**30. Resolution of disputes**

30.1 If dispute or difference of any kind shall arise between the Purchaser/Consignee and the supplier in connection with or relating to the contract, the parties shall make every effort to resolve the same amicably by mutual consultations.

30.2 If the parties fail to resolve their dispute or difference by such mutual consultation within twenty-one days of its occurrence, then, unless otherwise provided in the SCC, either the Purchaser/Consignee or the supplier may give notice to the other party of its intention to commence arbitration, as hereinafter provided the applicable arbitration procedure will be as per the Arbitration and Conciliation Act, 1996 of India. In the case of a dispute or difference arising between the Purchaser/Consignee and a domestic Supplier relating to any matter

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

arising out of or connected with the contract, such dispute or difference shall be referred to the sole arbitration of an officer in the Ministry of Law and Justice, appointed to be the arbitrator by the Secretary, Ministry of Health and Family Welfare. The award of the arbitrator shall be final and binding on the parties to the contract subject to the provision that the Arbitrator shall give reasoned award in case the value of claim in reference exceeds Rupees One lakhs (Rs. 1,00,000/)

30.3 Venue of Arbitration: The venue of arbitration shall be the place from where the contract has been issued.

### 31. **Applicable Law**

31.1 The contract shall be governed by and interpreted in accordance with the laws of India for the time being in force.

31.2 Jurisdiction

The courts at Chennai, Tamil Nadu shall have exclusive jurisdiction for all disputes and difference arising out of this contract.

### 32. **General/ Miscellaneous Clauses**

32.1 Nothing contained in this Contract shall be constructed as establishing or creating between the parties, i.e. the Supplier/its Indian Agent/AMC Provider on the one side and the Purchaser on the other side, a relationship of master and servant or principal and agent.

32.2 Any failure on the part of any Party to exercise right or power under this Contract shall not operate as waiver thereof.

32.3 The Supplier shall notify the Purchaser/Consignee /the Government of India of any material change would impact on performance of its obligations under this Contract.



32.4 Each member/constituent of the Supplier/its Indian Agent/AMC Provider shall be **jointly and severally liable** to and responsible for all obligations towards the Purchaser/Consignee/Government for performance of contract/services including that of its Associates/Sub Contractors under the Contract.

### 32.5 **Indemnities**

32.6 The Supplier/its Indian Agent/AMC Provider shall at all times, indemnify and keep indemnified the Purchaser/Government of India against all claims, damages, cost and expenses arising from the incorporation in or use of work of any such articles, processes or supplies made under this agreement. Supplier shall at all times indemnify the purchaser against all claims which may be made for any infringement of any Intellectual Property Rights (IPR) while providing its services under AMC or the Contract. However the liability of the Suppliers/its Indian Agents/AMC Providers raised on the above circumstances is limited to the overall contract value.

32.7 The Supplier/its Agent/AMC Provider shall, at all times, indemnify and keep indemnified the Purchaser/Consignee/Government of India against any claims in respect of any damages or compensation payable in consequences of any accident or injury sustained or suffered by its employees or agents or by any other third party resulting from or by any action, omission or operation conducted by or on behalf of the supplier/its associate/affiliate etc.

32.8 All claims regarding indemnity shall survive the termination or expiry of the contract.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

## SECTION – V

### SPECIAL CONDITIONS OF CONTRACT (SCC)

The following Special Conditions of Contract (SCC) will apply for this purchase. The corresponding clauses of General Conditions of Contract (GCC) relating to the SCC stipulations have also been incorporated below.

These Special Conditions will modify/substitute/supplement the corresponding (GCC) clauses.

Whenever there is any conflict between the provision in the GCC and that in the SCC, the provision contained in the SCC shall prevail.

#### **20. Taxes and Duties**

Any variation in statutory levies/taxes within the contractual delivery period shall be to HBL's account subject to production of documentary evidence and Govt. notifications by the Supplier & beyond contractual delivery period, upward variation shall be to Supplier's account. Unit Prices quoted by the bidder shall be firm and valid, irrespective of any statutory variations in Taxes/levies. In case any taxes, duties are not clearly specified in price bid then it will be presumed that no such tax/levy is applicable or payable. Blank field in Price Bid shall be treated as 'Inclusive' in the quoted price.



#### **ARBITRATION**

If any dispute, difference, question or disagreement arises between the parties hereto or their respective representatives at any time in connection with construction, meaning, operation, effect, interpretation or out of the contract or breach thereof, the parties shall seek to resolve such a dispute or difference by mutual consultation within a period of 30 days from the date on which the party raising the dispute, first communicated the same in writing to the other party. The existing directions, classifications, measurements, drawings and certificates of the Employer shall be final and binding upon the contractor during the progress of the works and shall not be set aside on account of non-observance of any formality, any omission, delay or error in proceeding in or about the same or on any other ground or for any reason.

In case the dispute is not settled by mutual consultation, then either party may refer the same to Arbitration by an Arbitral Tribunal consisting of three arbitrators. Each party shall appoint an arbitrator and the arbitrators so appointed shall appoint a third arbitrator who will act as presiding arbitrator.

The reference to arbitrator shall specify the matters which are in question, dispute or difference and only such dispute or differences of which the demand has been made be referred to arbitration. Notwithstanding the reference to arbitration, the contractor shall continue to duly perform his obligations under the contract.

The Award of the Arbitral Tribunal shall be final, conclusive and binding on the parties. The Arbitration shall be conducted in accordance with the provisions of Arbitration and Conciliation Act, 1996. The venue of the arbitration shall be at Chennai. The fees of the arbitrators shall be borne by the parties nominating them and the fee of the Presiding Arbitrator, costs and other expenses incidental to the arbitration proceedings shall be borne equally by the parties.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

**SECTION - VI  
LIST OF REQUIREMENTS**

SI no	Item (Package)	Equipment ID	Qty (Nos.)	Capacity / Size	EMD
1	Vial Washing Machine With Depyrogenating Tunnel	F2-VWD 01	1	200 Vials per minute	Rs.18,00,000/-
2	Vial Washing Machine With Depyrogenating Tunnel	F1-VWD 01	1	200 Vials per minute	
3	Vial Washing Machine With Depyrogenating Tunnel	F1-VWD 02	1	200 Vials per minute	
4	Vial sealing machine	F2-VSM 01	1	200 Vials per minute	
5	Vial sealing machine	F1-VSM 01	1	200 Vials per minute	
6	Vial sealing machine	F1-VSM 02	1	200 Vials per minute	

**Part II: Required Delivery Schedule:**

As mentioned in the schedule of Fiscal Aspects

**Part III: Scope of Incidental Services:**

Installation & Commissioning, Supervision, Demonstration, Trial run and Training etc. as specified in GCC Clause 13

**Part IV:** Turnkey (if any) as per details in General Technical Specification.

**Part V:** Annual Maintenance Contract (AMC) as per details in Technical Specification.

**Part VI: Required Terms of Delivery and Destination.**

**a) For Indigenous goods or for imported goods if supplied from India:  
At Consignee Site**

Insurance shall be borne by the Purchaser.

**b) For Imported goods directly from abroad:**



The foreign tenderers are required to quote their rates on DAP at Consignee site basis giving breakup of the price as per the Proforma prescribed in the Price Schedule.

The shipping arrangements shall be made in accordance with the instruction of Ministry of Shipping & Transport, New Delhi, India as detailed in Section XXII.

Insurance shall be borne by the Purchaser.

**Destination/Consignee details are given in Section XX**



Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

### Section – VII Technical Specifications

**Note 1:** Tenderer's attention is drawn to GIT clause 17 and GIT sub-clause 10.1 under heading (c) preparation of tenders. The tenderer is to provide the required details, information, confirmations, etc. accordingly failing that it's tender is liable to be ignored.

**Note 2:** General: Bidders are requested to make sure that they should attach the list of equipments for carrying out routine and preventive maintenance wherever asked for and should make sure that Electrical Safety Analyzer / Tester for Process equipments to periodically check the electrical safety aspects as per BIS Safety Standards IS-13540 which is also equivalent to IEC electrical safety standard IEC-60601 is a part of the equipments. If the Electrical Safety Analyzer/Tester is not available they should provide a commitment to get the equipments checked for electrical safety compliance with Electronic Regional Test Labs / Electronics Test and Development Centers across the country on every preventive maintenance call.

**Note 3:** OPTIONAL ITEMS: Bidders are requested to quote for all the available options as asked in the bidding document with reasonable pricing. However the pricing for optional items will not be considered for price comparison for ranking purpose. If the firm has not quoted for any optional item (except the items of turnkey- if any) their offer will be treated as TECHNICALLY RESPONSIVE if otherwise meeting the specification.

***Refer the following Annexures for the details on IRS & URS's***

**Annexure I: Installation Requirement Specification (IRS) and Specific Instructions  
Annexure II: User Requirement Specifications**

- A. Vial Vial Washing Machine With Depyrogenating Tunnel (F1-VFS 01)
- B. Vial Vial Washing Machine With Depyrogenating Tunnel (F1-VFS 02)
- C. Vial Vial Washing Machine With Depyrogenating Tunnel (F2-VFS 01)
- D. Vial sealing Machine (F1-VSM 01)
- E. Vial sealing Machine (F1-VSM 02)
- F. Vial sealing Machine (F2-VSM 01)



Note: Specifications packages in separate folder.

**Note:**

1. The available clear height inside any of the rooms is 3 m. Vendors to check suitability of installing their equipments in this available area and height and revert back with their views.

If no views are received from any vendors before or during the pre-bid meeting, it is assumed that the vendor is confident of installing their equipments with-in the area and height available. No further claims shall be entertained.

2. The extent of automation and optional additional features may vary during the pre-bid discussion.
3. The quantity of equipment mentioned in the list may vary during ordering.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

## GENERAL TECHNICAL SPECIFICATIONS

### GENERAL POINTS:

#### 1. Warranty:

- a) One year Comprehensive Warranty as per Conditions of Contract of the TE document for complete equipment and Turnkey (if any) Work from the date of satisfactory installation, commissioning, trial run & handing over of equipment to CONSIGNEE.
- b) 98% up time Warranty of complete equipment with extension of Warranty period by double the downtime period on 24 (hrs) X 7 (days) X 365 (days) basis.
- c) All software updates should be provided free of cost during Warranty period.

#### 2. After Sales Service:



After sales service centre should be available at the city of CONSIGNEE on 24 (hrs) X 7 (days) X 365 (days) basis. Complaints should be attended properly, maximum within 48 hrs. The service should be provided by Tenderer/Indian Agent. Undertaking by the Principals that the spares for the equipment shall be available for at least 10 years from the date of supply. However if the manufacturer/agent does not have the service centres in India will have to set up the same within 45 days after award of the contract.

#### 3. Training:

On Site training to operators/ Technicians/ staff is to be provided by Principal/ Indian Agents (if they have the requisite know-how) for operation and maintenance of the equipment to the satisfaction of the consignee.

#### 4. Annual Maintenance Contract (AMC) of subject equipment with Turnkey (if any):



- a) The cost of Annual Maintenance Contract (AMC) which includes preventive maintenance including testing & calibration as per technical/ service /operational manual of the manufacturer, labour after satisfactory completion of Warranty period may be quoted for next 2 years on yearly basis for complete equipment and Turnkey (if any). The supplier shall visit each consignee site as recommended in the manufacturer's technical/ service /operational manual, but at least once in three months during the AMC period. However incase of break down, the vendor shall attend to the problem within 48 hours from the intimation from the purchaser.
- b) The cost of AMC may be quoted along with taxes applicable on the date of Tender Opening. The taxes to be paid extra, to be specifically stated. In the absence of any such stipulation the price will be taken inclusive of such taxes and no claim for the same will be entertained later.
- c) Cost of AMC will be added for Ranking/Evaluation purpose.
- d) The payment of AMC will be made on six monthly basis, after satisfactory completion of said period, duly certified by end user .
- e) There will be 98% uptime warranty during AMC period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend AMC period by double the downtime period.
- f) During AMC period, the supplier is required to visit at each consignee's site at least once in 3 months commencing from the date of the successful completion of warranty period for preventive maintenance of the goods.
- g) All software updates should be provided free of cost during AMC.
- h) Failure of the above [4. e) to 4. g)] by the supplier, may lead to the forfeiture of the Bank Guarantee for AMC.
- i) The payment of AMC will be made as stipulated in GCC Clause 21.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

j) the cost of any spares required during the preventive maintenance/ break down maintenance in the AMC period will be paid extra at actual by the purchaser.

***Turnkey (if any):***

- (i) The Tenderer shall examine the existing site where the equipment is to be installed.
- (ii) ***TurnKey (if any) comprises of Supply, Installation, Commissioning and validation of the Vial Washing machine with Depyrogenating Tunnels and Vial Sealing Machines.***
- (iii) ***Tenderers to quote prices indicating break-up of prices of the Machine.***
- (iv) ***The Turnkey costs (if any) may*** be quoted (Inclusive of all taxes /duties) in Indian Rupee will be added for Ranking Purpose.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**Section – VIII  
Quality Control Requirements (for each schedule)**

(Proforma for equipment and quality control employed by the manufacturer(s) Tender Reference No.

Date of opening



Time

Name and address of the Tenderer:

Note: All the following details shall relate to the manufacturer(s) for the goods quoted for.

- 01 Name of the manufacturer
  - a. Full postal address
  - b. Full address of the premises
  - c. Email ID
  - d. Telephone number
  - e. Fax number
- 02 Plant and machinery details
- 03 Manufacturing process details
- 04 Monthly (single shift) production capacity of goods quoted for
  - a. normal
  - b. maximum
- 05 Total annual turn-over (value in Rupees) for the last three calendar years excluding the year of tender opening:
- 06 Quality control arrangement details
  - a. for incoming materials and bought-out components
  - b. for process control
  - c. for final product evaluation
- 07 Test certificate held
  - a. . type test
  - b. . BIS/ISO certification
  - c. . any other
- 08 Details of staff
  - a. technical
  - b. skilled
  - c. unskilled
- 09 Please furnish documentation details with clarifications etc as asked for at the end of the equipment specification.

**Signature and seal of the Tenderer**

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**Section – IX  
Qualification Criteria (For every schedule Quoted)**



1. The tenderer:

Has to be a manufacturer of all the tendered equipment.

OR



Has to be an authorised Indian representative of the equipment manufacturer/s of all the tendered equipment."

2. In case the manufacturer of any of the tendered equipment is of foreign origin, the manufacturer should have a Permanent Establishment or Authorised Representative in India for carrying out the activities of Clearing, Forwarding, Transportation, Installation, Commissioning, Qualification, Training and Warranty.
3. The Tenderer should have supplied, installed & commissioned successfully at-least two vial washing machines with Depyrogenation tunnel and two vial sealing machines with a minimum capacity of 200vials/minute in the last seven years prior to the date of Tender Opening in any pharma/bio pharma formulations facility. (Purchase order, Installation certificate or Completion certificate of the vial washing machine with Depyrogenation tunnel and vial sealing machines to be attached).
4. The Clients of the tenderer list must include at-least two facilities approved from national regulatory body (NRA) or international regulatory bodies (viz., US-FDA / UK-MHRA / WHO / EU). List-out the experience under section X C.
5. The average annual turnover of the tenderer must be minimum INR.45 Million (or equivalent in Foreign Currency) during the last three financial year (2011-12, 2012-13 and 2013-14). Furnish the information under section X B. The Balance sheet and Profit & loss account statement to be provided.
6. Net worth of the Tenderer should be positive during the last three financial years (2011-12, 2012-13 and 2013-14).The Profit & loss account statement to be furnished.
7. The Manufacturer and authorized Indian agent should jointly have at least three years of experience in installing and commissioning of vial washing machine with Depyrogenating tunnel & vial sealing machine in India with record of proof ( Record of Proof : Agreement between the two parties to install and commission the vial washing machine with Depyrogenating tunnel & vial sealing machine in India) The detailed list of service / maintenance team in India with their experience to be enclosed along with the bid document.

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>


**Note:**

- In support of above the Tenderer shall furnish the details in the below tables.
- The manufacturer as well as the Tenderer/ Indian Agent shall furnish Satisfactory Performance cum Installation Certificate/purchase orders/bill of entry in respect of above, duly translated in English and duly notarized in the country of origin, along with the tender.
- The Tenderer shall furnish a brief write-up, packed with adequate data explaining and establishing his available capacity/capability (both technical and financial) to perform the Contract (if awarded) within the stipulated time period, after meeting all its current/present commitments. The Tenderer shall also furnish details of Equipment and Quality Control in the enclosed Section below.
- The Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of Tender opening certified by a Chartered Accountant should be submitted as part of the tender
- Notwithstanding anything stated above, the Purchaser reserves the right to assess the Tenderer's capability and capacity to perform the contract satisfactorily before deciding on award of Contract, should circumstances warrant such an assessment in the overall interest of the Purchaser. The Purchaser reserves the right to ask for a free demonstration of the quoted equipment to similar/identical specification at a pre determined place acceptable to the purchaser for determining technical responsiveness, before the opening of the Price Bid.
- The Purchaser also reserves the right to assess the Tenderer's capability and capacity to perform the contract satisfactorily by inspecting their facility. Such assessment shall be done before opening of the Price Bid and the assessment report shall form part of TCTR.

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**PROFORMA:**


<b>SECTION (A). GENERAL INFORMATION:</b>		
1	Name of Company	
2	Registration No.	
3	Number of Years in Operation	
4	Registered Address	
5	Operating Address	
6	Telephone No	
7	Telefax	
8	Email Address	
9	SERVICE TAX No.	
10	PAN No.	
11	TIN No.	

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

### SECTION (B). FINANCE



1	<b>Name &amp; Address of Banks and Branches used :</b>	
1.1		
1.2		
1.3	Documentary evidence (duly signed & stamped) must be enclosed.	<input type="checkbox"/> Yes <input type="checkbox"/> no
2	What is your average annual invoiced sales value (based on past previous 5 year's records) for each of the type of equipments under consideration.	
	Equipment Name: ----- (If more then one equipment, enclose the same separately)	
2.1	Year 1	_____ (Value in Lakhs)
	Year 2	_____ (Value in Lakhs)
	Year 3	_____ (Value in Lakhs)
	Year 4	_____ (Value in Lakhs)
	Year 5	_____ (Value in Lakhs)
2.2	Documentary evidence (duly signed & stamped) must be enclosed.	<input type="checkbox"/> Yes <input type="checkbox"/> no
3	<b>Annual Turnover of the Firm/ company:</b>	
3.1	2013 – 2014:	_____ (Value in Lakhs)
	2012 – 2013:	_____ (Value in Lakhs)
	2011 – 2012:	_____ (Value in Lakhs)
3.2	Documentary evidence (duly signed & stamped) must be enclosed.	<input type="checkbox"/> Yes <input type="checkbox"/> no
4	Bidders are to submit copy of valid current Income Tax Return submitted, Sales Tax Registration failing which their offer may be liable to be rejected.	<input type="checkbox"/> Yes <input type="checkbox"/> no



Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13



**SECTION (C) EXPERIENCE:**

1	<b>Past Project Experience:</b>  1. The Tenderer should have supplied, installed & commissioned successfully at-least two vial washing machines with Depyrogenation tunnel and two vial sealing machines with a minimum capacity of 200vials/minute in the last seven years prior to the date of Tender Opening in any pharma/bio pharma formulations facility. (Purchase order, Installation certificate or Completion certificate of the vial washing machine with Depyrogenation tunnel and vial sealing machines to be attached). 2. The Clients of the tenderer list must include at-least two facilities approved from national regulatory body (NRA) or international regulatory bodies (viz., US-FDA / UK-MHRA / WHO / EU). List-out the experience under section X C.					
Sr. No.	Year awarded	Project Name	Equipments Supplied	CONTRACT VALUE (INR)	CLIENT NAME & REFERENCE (Contact details)	Facility Approved by: (Name of approving agency)
1.1						
1.2						
1.3						
1.4						
1.5						
1.6						
1.7						
1.8						
1.9						
1.10						
<b>Documentary evidence of work completion certificate duly signed &amp; stamped must be enclosed including the evidence of the facility having approved by regulatory agencies.</b>						<input type="checkbox"/> Yes <input type="checkbox"/> no
2	<b>Details of Ongoing project:</b>					
S. No.	Year awarded	Project Name	Equipments Supplied	CONTRACT VALUE (INR)	CLIENT NAME & REFERENCE (Contact details)	Remarks
2.1						
2.2						
2.3						
2.4						
2.5						
<b>Documentary evidence of the same to be enclosed</b>						<input type="checkbox"/> Yes <input type="checkbox"/> no


Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

### SECTION (D). QUALITY

<b>1</b>	<b>ISO CERTIFICATION</b>	
	<p>Is your company ISO certified, if so mention the certification number and enclose the photocopy of the certificate:</p> <p>ISO_____</p> <p>ISO_____</p> <p>ISO_____</p>	<input type="checkbox"/> Yes <input type="checkbox"/> no
<b>2</b>	Enclose the company Quality policy	<input type="checkbox"/> Yes <input type="checkbox"/> no
<b>3</b>	<p>The equipment supplied should comply with the following guidelines / standards.</p> <p>Note: Subject to the kind of equipment supplied.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> no
<b>3.1</b>	<b>cGMP-Regulations</b>	<input type="checkbox"/> Yes <input type="checkbox"/> no
3.1.1	EU-GMP-Guideline Part 1, Annexes 1, 11 & 15	<input type="checkbox"/> Yes <input type="checkbox"/> no
3.1.2	Code of Federal Regulations (CFR) 21, Part 210: cGMP in Manufacturing, Processing, Packing and Holding of Drugs: General.	<input type="checkbox"/> Yes <input type="checkbox"/> no
3.1.3	21 CFR Part 211: Current Good Manufacturing Practice for finished Pharmaceuticals.	<input type="checkbox"/> Yes <input type="checkbox"/> no
3.1.4	Schedule "M" GMP	<input type="checkbox"/> Yes <input type="checkbox"/> no
3.1.5	21 CFR Part 11: Electronic Records; Electronic Signatures	<input type="checkbox"/> Yes <input type="checkbox"/> no
<b>3.2</b>	<b>FDA Guidance for Industry</b>	<input type="checkbox"/> Yes <input type="checkbox"/> no
3.2.1	Sterile Drug Products Produced by Aseptic Processing	<input type="checkbox"/> Yes <input type="checkbox"/> no
<b>3.3</b>	<b>GAMP</b>	<input type="checkbox"/> Yes <input type="checkbox"/> no

Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00  Date : 2014.11.13</b>


3.3.1	The Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture, Vol. 5.	<input type="checkbox"/> Yes <input type="checkbox"/> no
<b>3.4</b>	<b>CE Conformity</b>	
3.4.1	Deleted	<input type="checkbox"/> Yes <input type="checkbox"/> no
<b>3.5</b>	<b>Operating safety act</b>	
3.5.1	The requirements of the Operating safety act must be observed.	<input type="checkbox"/> Yes <input type="checkbox"/> no
<b>3.6</b>	<b>ISO 14664</b>	
3.6.1	Clean rooms and Associated Controlled Environment	<input type="checkbox"/> Yes <input type="checkbox"/> no

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
Project No : 120310	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	Revision : 00 Date : 2014.11.13

<b>Section (E). ATTACHMENTS</b>		
S. No.	Please provide the following documents in your submissions:	Enclosed
1	Company Brochure / Literature	<input type="checkbox"/> Yes <input type="checkbox"/> no
2	Product profile	<input type="checkbox"/> Yes <input type="checkbox"/> no
3	Technical Details of equipments	<input type="checkbox"/> Yes <input type="checkbox"/> no
4	Name & Address of Banks and Branches used : (duly signed & stamped)	<input type="checkbox"/> Yes <input type="checkbox"/> no
	<b>Annual turnover for the following years</b>	
5	2013 - 2014 : Balance sheet (duly signed & stamped)	<input type="checkbox"/> Yes <input type="checkbox"/> no
	2012 - 2013 : Balance sheet (duly signed & stamped)	<input type="checkbox"/> Yes <input type="checkbox"/> no
	2011 – 2012: Balance sheet (duly signed & stamped)	<input type="checkbox"/> Yes <input type="checkbox"/> no
6	current Income Tax Return	<input type="checkbox"/> Yes <input type="checkbox"/> no
	Sales Tax Registration	<input type="checkbox"/> Yes <input type="checkbox"/> no
7	Past project experience: Completion certificate:	<input type="checkbox"/> Yes <input type="checkbox"/> no
8	Ongoing project details.	<input type="checkbox"/> Yes <input type="checkbox"/> no
9	ISO Certificates	<input type="checkbox"/> Yes <input type="checkbox"/> no
10	Company policies	<input type="checkbox"/> Yes <input type="checkbox"/> no
11	Equipment list / scope of supply	<input type="checkbox"/> Yes <input type="checkbox"/> no

### Signature and seal of the Tenderer

**\*\* The documentary proof will be a certificate (enclosed) from the consignee/end user/purchaser with cross-reference of order no. and date in the certificate duly notarised certification authenticating the correctness of the information furnished. If at any time, information furnished is proved to be false or incorrect, the earnest money and or performance security furnished will be forfeited .such certificates from a third party or middleman other than actual end user/purchaser will not be accepted.**



Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.10.xx

**FORMAT OF PERFORMANCE CERTIFICATE**

**To whom it may concern**

Date. \_\_\_\_\_

Certified that M/s -----(name & address of the manufacturer) supplied us -----Nos (indicate quantity) of equipment, -----(indicate name of the equipment) against our order no -----dt -----(please indicate order no & date as figuring in the performance statement). The equipment was installed, commissioned & handed over to us on -----(indicate date) & since then the equipment has been working to our entire satisfaction.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.10.xx

**Section – X  
TENDER FORM**

Date \_\_\_\_\_  
To \_\_\_\_\_

**HLL Biotech Limited, Chennai**

Ref. Your TE document No. \_\_\_\_\_ dated \_\_\_\_\_  
We, the undersigned have examined the above mentioned TE document, including amendment/corrigendum No. \_\_\_\_\_, dated \_\_\_\_\_ (if any), the receipt of which is hereby confirmed. We now offer to supply and deliver \_\_\_\_\_ (Description of goods and services) in conformity with your above referred document for the sum of \_\_\_\_\_ (total tender amount in figures and words), as shown in the price schedule(s), attached herewith and made part of this tender.

If our tender is accepted, we undertake to supply the goods and perform the services as mentioned above, in accordance with the delivery schedule specified in the List of Requirements.

We further confirm that, if our tender is accepted, we shall provide you with a performance security of required amount in an acceptable form in terms of GCC clause 5, read with modification, if any, in Section - V – “Special Conditions of Contract”, for due performance of the contract.

We agree to keep our tender valid for acceptance as required in the GIT clause 19, read with modification, if any in Section - III – “Special Instructions to Tenderers” or for subsequently extended period, if any, agreed to by us. We also accordingly confirm to abide by this tender up to the aforesaid period and this tender may be accepted any time before the expiry of the aforesaid period. We further confirm that, until a formal contract is executed, this tender read with your written acceptance thereof within the aforesaid period shall constitute a binding contract between us.


We further understand that you are not bound to accept the lowest or any tender you may receive against your above-referred tender enquiry.

We confirm that we do not stand deregistered/banned/blacklisted by any Govt. Authorities.

We confirm that we fully agree to the terms and conditions specified in above mentioned TE document, including amendment/ corrigendum if any

\_\_\_\_\_  
**(Signature with date)**

**(Name and designation) Duly authorised to sign tender for and on behalf of**

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
Project No : 120310	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	Revision : 00 Date : 2014.10.xx

**SECTION – XI A PRICE SCHEDULE**  
**i) PRICE SCHEDULE FOR DOMESTIC GOODS OR GOODS OF FOREIGN  
ORIGIN LOCATED WITHIN INDIA**

1	2	3	4	5					6	
				Price per unit (Rs.)						
Schedule	Brief Description of Goods	Country of Origin	Quantity (Nos.)	Ex - factory/ Ex -warehouse /Ex - showroom /Off - the shelf (a)	Excise Duty (if any) [%age & value] (b)	CST/ VAT (if any) [%age & value] ©	Packing and Forwarding charges (d)	Incidental Services (including Installation & Commissioning, Supervision, Demonstration , Training, Documentation and Qualification) at the Consignee's site (e)	Unit Price (at Consignee Site) basis (f) =a+b+c+d+e	Total Price (at Consignee Site) basis (Rs.) 4 x 5(f)

NB: Unit price shall be written in figures and words

Total Tender price in Rupees: \_\_\_\_\_

***In words:***

\_\_\_\_\_

*The above price shall be without insurance .Insurance shall be under Purchaser's scope.*

**Note: -**

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.
2. The charges for AMC after warranty shall be quoted separately as per Section – XI – Price Schedule C

**Name** \_\_\_\_\_


**Business Address** \_\_\_\_\_

**Place:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Signature of Tenderer** \_\_\_\_\_

**Seal of the Tenderer** \_\_\_\_\_

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
	Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09

**SECTION – XI B PRICE SCHEDULE**  
**i) PRICE SCHEDULE FOR GOODS TO BE IMPORTED FROM ABROAD**

1	2	3	4	5									6
				Price per unit (Currency)									
Schedule	Brief Description of Goods	Country of Origin	Quantity (Nos.)	Gross FOB price at sea / air port of Lading (inclusive of Agency commission)	Amount and percentage of Agency Commission **	Net FOB (excluding Agency Commission) (a-b)	Freight	Net CFR Port of destination by Air/sea (c+d)	Customs Clearance & Handling Charges **	Loading / unloading / inland transportation & incidental cost till consignee's site **	Installation, commissioning, supervision, Demonstration, training Documentaion and Qualification at the consignee's site **	Unit price on DAP basis at consignee's site (a+d+f+g+h)	Total price on DAP basis at consignee's site 4X 5 (i)
				(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)

\*\* To be paid in Indian Currency (Rs.) or to the principal in their currency  
Total DAP at Consignee site price in figures:

\_\_\_\_\_

And in words:


\_\_\_\_\_

**Note: -**

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.
2. The charges for Annual Maintenance Contract (AMC) after warranty shall be quoted separately as per Section – XI – Price Schedule C
3. The Tenderer will be fully responsible for the safe arrival of the goods at Consignee Site.
4. The bidders break up of prices under various columns are for comparison of prices up to delivery of goods at consignee's site for tender evaluation and will be allowed on actual basis subject to bidders quoted prices as ceiling under various heads which will be adjusted later against balance payment.
5. The quoted price should be bidder's best lowest rate supported with original proforma invoice from the foreign manufacturers Indian Agent to be paid in Indian Currency.

Signature \_\_\_\_\_ of \_\_\_\_\_ Tenderer \_\_\_\_\_  
Name \_\_\_\_\_  
Business Address \_\_\_\_\_  
Place: \_\_\_\_\_  
Signature of Tenderer \_\_\_\_\_  
Date: \_\_\_\_\_  
Seal of the Tender \_\_\_\_\_



Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>  <b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	nne pharmaplan®
Project No : 120310		Revision : 00 Date : 2014.11.13

**SECTION – XI C PRICE SCHEDULE  
PRICE SCHEDULE FOR ANNUAL MAINTENANCE CONTRACT AFTER WARRANTY  
PERIOD**

1	2	3	4		5
Schedule No.	BRIEF DESCRIPTION OF GOODS	QUANTITY. (Nos.)	Annual Maintenance Contract Cost for Each Unit year wise*.		Total Annual Maintenance Contract Cost for 2 Years [3 x (4A+4B)]
			1 <sup>st</sup>	2 <sup>nd</sup>	
			A	B	

\* After completion of Warranty period

**NOTE:-**

1. In case of discrepancy between unit price and total prices, THE UNIT PRICE shall prevail.
2. The cost of Annual Maintenance Contract (AMC) which includes preventive maintenance including testing & calibration as per technical/ service /operational manual, labour and spares, after satisfactory completion of Warranty period may be quoted for next 2 years on yearly basis for complete equipment and Turnkey (if any).
3. The cost of AMC may be quoted along with taxes applicable on the date of Tender Opening. **The taxes to be paid extra, to be specifically stated. In the absence of any such stipulation the price will be taken inclusive of such taxes and no claim for the same will be entertained later.**
4. Cost of AMC will be added for Ranking/Evaluation purpose.
5. The payment of AMC will be made as per clause GCC clause 21.1 (D).
6. The uptime warranty will be 98 % on 24 (hrs) X 7 (days) X 365 (days) basis or as stated in Technical Specification of the TE document.
7. All software updates should be provided free of cost during AMC period.
8. The stipulations in Technical Specification will supersede above provisions
9. The supplier shall keep sufficient stock of spares required during Annual Maintenance Contract period. In case the spares are required to be imported, it would be the responsibility of the supplier to import and get them custom cleared and pay all necessary duties.
10. Agency commission may be shown in separate column in price schedule.
11. The cost of spares required during the preventive maintenance/ breakdown maintenance during the AMC shall be paid extra at actual by the supplier.

Name \_\_\_\_\_


Business Address \_\_\_\_\_

Place: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Tenderer \_\_\_\_\_

Seal of the Tenderer \_\_\_\_\_

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>  <b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>		<b>Revision : 00 Date : 2014.11.13</b>

**SECTION – XI D PRICE SCHEDULE  
PRICE SCHEDULE FOR TURNKEY (IF ANY)**

Schedule No.	BRIEF TURNKEY (IF ANY) DESCRIPTION OF GOODS	Turnkey (if any) price

Note: -

1. The cost of Turnkey (if any) as per Technical Specification (Section VII) may be quoted on lump sum inclusive of all taxes & duties. Cost of Turnkey (if any) will be added for Ranking/Evaluation purpose.
2. The payment of Turnkey (if any) will be made as per clause GCC clause 21.1 (c).
3. The stipulations in Technical Specification will supersede above provisions

**Name** \_\_\_\_\_


**Business Address** \_\_\_\_\_

**Place:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Signature of Tenderer** \_\_\_\_\_


**Seal of the Tenderer** \_\_\_\_\_

Client : 	<p style="text-align: center;"><b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b></p> <p style="text-align: center;"><b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b></p>	nne pharmaplan®
Project No : 120310		Revision : 00 Date : 2014.11.13

**SECTION – XII  
QUESTIONNAIRE**

**Fill up the Section XIX – Check List for Tenderers and enclose with the Tender**

1. The tenderer should furnish specific answers to all the questions/issues mentioned in the Checklist. In case a question/issue does not apply to a tenderer, the same should be answered with the remark “not applicable”
2. Wherever necessary and applicable, the tenderer shall enclose certified copy as documentary proof/ evidence to substantiate the corresponding statement.
3. In case a tenderer furnishes a wrong or evasive answer against any of the question/issues mentioned in the Checklist, its tender will be liable to be ignored.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**SECTION – XIII  
BANK GUARANTEE FORM FOR EMD**

Whereas \_\_\_\_\_ (hereinafter called the “Tenderer”) has submitted its quotation dated \_\_\_\_\_ for the supply of \_\_\_\_\_ (hereinafter called the “tender”) against the purchaser’s tender enquiry No. \_\_\_\_\_ Know all persons by these presents that we \_\_\_\_\_ of \_\_\_\_\_ (Hereinafter called the “Bank”) having our registered office at \_\_\_\_\_ are bound unto \_\_\_\_\_ (hereinafter called the “Purchaser) in the sum of \_\_\_\_\_ for which payment will and truly to be made to the said Purchaser, the Bank binds itself, its successors and assigns by these presents. Sealed with the Common Seal of the said Bank this \_\_\_\_\_ day of \_\_\_\_\_ 20\_\_\_\_. The conditions of this obligation are:

- (1) If the Tenderer withdraws or amends, impairs or derogates from the tender in any respect within the period of validity of this tender.
- (2) If the Tenderer having been notified of the acceptance of his tender by the Purchaser during the period of its validity:-
  - a) fails or refuses to furnish the performance security for the due performance of the contract.  
or
  - b) fails or refuses to accept/execute the contract.  
or
  - c) if it comes to notice that the information/documents furnished in its tender is incorrect, false, misleading or forged


We undertake to pay the Purchaser up to the above amount upon receipt of its first written demand, without the Purchaser having to substantiate its demand, provided that in its demand the Purchaser will note that the amount claimed by it is due to it owing to the occurrence of one or both the two conditions, specifying the occurred condition(s).

This guarantee will remain in force for a period of forty-five days after the period of tender validity and any demand in respect thereof should reach the Bank not later than \_\_\_\_\_ day of \_\_\_\_\_ 20\_\_\_\_.

\_\_\_\_\_  
(Signature of the authorised officer of the Bank)

\_\_\_\_\_  
Name and designation of the officer

\_\_\_\_\_  
Seal, name & address of the Bank and address of the Branch

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

**SECTION – XIV  
MANUFACTURER’S AUTHORISATION FORM**

To

---

**HLL Biotech Limited, Chennai**

Dear Sirs,

Ref. Your TE document No \_\_\_\_\_, dated \_\_\_\_\_

We, \_\_\_\_\_ who are proven and reputable manufacturers of \_\_\_\_\_ (name and description of the goods offered in the tender) having factories \_\_\_\_\_ at \_\_\_\_\_, hereby authorise Messrs \_\_\_\_\_ (name and address of the agent) to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than Messrs. \_\_\_\_\_ (name and address of the above agent) is authorised to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also hereby extend our full warranty, AMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

Yours faithfully,


---

[Signature with date, name and designation]  
for and on behalf of Messrs \_\_\_\_\_

[Name & address of the manufacturers]

**Note:**

1. This letter of authorisation should be on the letter head of the manufacturing firm and should be signed by a person competent and having the power of attorney to legally bind the manufacturer.
2. Original letter may be sent.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

**SECTION – XV (A)**

**BANK GUARANTEE FORM FOR ADVANCE BANK GUARANTEE**

Ref.....

Date.....

Bank Guarantee No....

To


HLL Biotech Ltd.,  
Module 013-015,  
Ticel Biopark Campus,  
CSIR Road, Taramani,  
Chennai – 600 113.

Dear Sirs,

In consideration of the HLL Biotech Ltd., hereinafter referred to as 'HBL', which expression shall unless repugnant to the context or meaning thereof include its successors, executors, administrators and assigns, having awarded to M/s. \_\_\_\_\_ having its registered office at \_\_\_\_\_ hereinafter referred as the 'Supplier', which expression shall unless repugnant to the context or meaning thereof, include its successors, Administrators, executors and assigns, a contract hereinafter referred to as the 'Order' for \_\_\_\_\_ referred to as the 'Supply and Services' on terms and conditions set out, inter-alia in the HBL's Order No. \_\_\_\_\_ dated \_\_\_\_\_ valued \_\_\_\_\_ at \_\_\_\_\_ (in words & figures) and as the HBL having agreed to make a payment against the above ORDER, to the Supplier amounting to Rs. \_\_\_\_\_ (in words & figures) as an advance against Bank Guarantee to be furnished by the Supplier, the said advance to be adjusted against the supply and services to be performed by the Supplier, we \_\_\_\_\_ hereinafter referred to as the 'Bank' which expressions shall, unless repugnant to the context or meaning thereof, include its successors, administrators, executors and assigns **having our office at \_\_\_\_\_ do hereby undertake to give the irrevocable and unconditional guarantee and** do hereby undertake to pay the HBL on first demand without any demur, **reservation, contest recourse and protest and without reference to the Supplier** any and all monies payable by the Supplier by reason of any breach by the said Supplier of any of the terms and conditions of the said order to the extent of Rs. \_\_\_\_\_ (in words & figures) till the said advance is adjusted as aforesaid at any time up to \_\_\_\_\_. We agree that the guarantee herein contained shall continue to be enforceable till the sum due to the HBL on account of the said advance is adjusted/recovered in full as aforesaid or till the HBL discharges this guarantee.

The HBL shall have the fullest liberty without affecting in any way the liability of the Bank under this guarantee, from time to time vary the advance or to extend the time for performance of the supply and services by the Supplier. The Bank shall not be released from its liability under these presents by any exercise of the HBL of the liberty with reference to the matter aforesaid.

The HBL shall have the fullest liberty, **without reference to Supplier and** without affecting this guarantee to postpone **for any time or** from time to time the exercise of any powers vested in them or of any right which they might have against the Supplier, and to exercise the same at any time in any manner, and either to enforce or to forebear to enforce any **power**, covenants contained or implied in the order between the HBL and the Supplier or any other course or remedy or security available to the HBL and the Bank shall not be released of its obligations under these presents by any exercise by the HBL of its liberty with reference to matters aforesaid or any of them or by reason of any other act or forbearance or other acts of omission or commission on the part of the HBL or any other indulgence shown by the HBL or by any other matter or thing whatsoever which under law would, but for this provision, have the effect of relieving the Bank Guarantee.

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**The right of HBL to recover the outstanding sum of advance with applicable costs up to Rs. \_\_\_\_\_ from the bank in the manner aforesaid will not be affected or suspended by reason of the fact that any dispute or disputes is or are pending before any officer, tribunal or court and any demand made by HBL on the Bank shall be conclusive and binding.**

The Bank further undertakes not to revoke this guarantee during its currency without prior and written consent of the **HBL and further agrees that the guarantee contained shall continue to be enforceable till the HBL discharges this guarantee.**

The Bank also agrees that the HBL shall at its option is entitled to enforce this guarantee against the bank as principal debtors, in first instance, notwithstanding any other security or guarantee that **HBL** may have in relation to the Supplier's liabilities of the said advance.

Notwithstanding anything contained herein above, our liability under this guarantee is restricted to as Rs. \_\_\_\_\_ (in words & figures) and it will remain in force up to and including \_\_\_\_\_ (date of completion of supply and services) and shall be extended from time to time for such periods as may be advised by M/s..... on whose behalf this guarantee has been given.

Therefore, we hereby affirm that we are guarantors and responsible to you on behalf of the Supplier up to a total amount of \_\_\_\_\_ (amount of guarantees in words and figures) and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the purchase order and without caveat or argument, any sum or sums within the limits of (amount of guarantee) as aforesaid, without your needing to prove or show grounds or reasons for your demand or the sum specified therein.

This Guarantee is valid until \_\_\_\_\_ day \_\_\_\_\_.

**We have power to issue this guarantee in your favour under Memorandum and Articles of Association and the undersigned has full power to do under the Power of Attorney / Resolution of Board of Directors dated.....granted to him by the Bank.**


Dated.....this.....day of.....20

Signed by

Place:

(Person duly authorised by Bank)

**Witness :**

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**SECTION – XV (B)**

**BANK GUARANTEE FORM FOR PERFORMANCE SECURITY**

To

HLL Biotech Ltd.,  
Module 013-015,  
TiceI Biopark Campus,  
CSIR Road, Taramani,  
Chennai – 600 113.

1. In consideration of HLL Biotech Limited (hereinafter called “HBL”) having agreed under the terms and conditions of Order No..... dated..... made between ..... (here in after called “the said contractor(s)”) for the ..... work (herein after called “the said agreement”) for compliance of his obligation in accordance with the terms and conditions in the said agreement.

We ..... (indicate the name of the Bank) (herein after referred to as “as Bank) hereby undertake to pay to the HBL and amount not exceeding Rs..... (Rupees..... only) on demand by HBL.

2. We ..... (Indicate the name of the Bank) do hereby undertake to pay the amount due and payable under this Guarantee without any demure, merely on a demand from HBL stating that the amount claimed is required to meet the recoveries due or likely to be due from the said contractor(s). any such demand made on the Bank shall be conclusive as regards the amount due and payable by the bank under this Guarantee. However, our liability under this guarantee shall be restricted to an amount not exceeding Rs..... (Rupees..... only).


3. We undertake to pay to HBL any money so demanded notwithstanding any dispute or disputes raised by the contractor (s) in any suit or proceeding pending before any court or Tribunal relating thereto our liability under this present being absolute and unequivocal.

The payment made by us under this guarantee shall be valid discharge of our liability for payment to there-under and the contractor(s) shall have no claim against us making such payment.

4. We ..... (Indicate the name of Bank) further agree that the guarantee herein contained shall remain in full force and effect during the period that would be taken for the performance of the said agreement and that it shall continue to be enforceable till all the dues of HBL under or by virtue of the said agreement have been fully paid and its claims satisfied or discharged or till Engineer-in-charge on behalf of HBL Certified that the terms and conditions of the said Agreement have been fully and properly carried out by the said contractor(s) accordingly discharges this guarantee.

5. We..... (Indicate the name of Bank) further agree with HBL that HBL shall have the fullest liberty without our consent and without affecting any manner our obligations hereunder to vary any of the terms and conditions of the said agreement or to extend time of performance by the said contractor(s) from time to time or to postpone for any of the powers exercisable by HBL against the said contractor(s) and to forebear or enforce any of the terms and conditions relating to the said agreement we shall not be relieved from our liability by reasons of any such variation or extension being granted to the said contractor(s) or for any forbearance act of omission on that part of the HBL or any indulgence by HBL to the said contract(s) or by any such matter or thing whatsoever which under the law relating to sureties would, but for this provision, have effected or so relieving us.




<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

6. The guarantee will not be discharged due to the change in the constitution of the Bank or the contractor(s).
7. We..... (indicate the name of Bank) lastly undertake not to revoke this guarantee except with the previous consent of HBL in writing.
8. This guarantee shall be valid up to ..... unless extended on demand by HBL. Notwithstanding anything mentioned above our liability against this Guarantee is restricted to Rs..... (Rupees.....only) and unless a claim in writing is lodged with us within six months of the date of expiry or the extended date of expiry of this guarantee, all our liabilities under the Guarantee shall stand discharged.

Dated the ..... day of 20....

For .....  
(Indicate the name of Bank)

.....  
Seal, name & address of the Bank and address of the Branch

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

**SECTION – XVI  
CONTRACT FORM - A**

**CONTRACT FORM FOR SUPPLY, INSTALLATION, COMMISSIONING, VALIDATION, HANDING  
OVER, TRIAL RUN, TRAINING OF OPERATORS & WARRANTY OF GOODS**

HLL Biotech Limited


Contract No \_\_\_\_\_ dated \_\_\_\_\_

**This is in continuation to this office's Notification of Award No \_\_\_\_\_ dated \_\_\_\_\_**

1. Name & address of the Supplier: \_\_\_\_\_
2. Purchaser's TE document No \_\_\_\_\_ dated \_\_\_\_\_ and subsequent Amendment No \_\_\_\_\_, dated \_\_\_\_\_ (if any), issued by the purchaser
3. Supplier's Tender No \_\_\_\_\_ dated \_\_\_\_\_ and subsequent communication(s) No \_\_\_\_\_ dated \_\_\_\_\_ (if any), exchanged between the supplier and the purchaser in connection with this tender.
4. In addition to this Contract Form, the following documents etc, which are included in the documents mentioned under paragraphs 2 and 3 above, shall also be deemed to form and be read and construed as integral part of this contract:
  - (i) General Conditions of Contract;
  - (ii) Special Conditions of Contract;
  - (iii) List of Requirements;
  - (iv) Technical Specifications;
  - (v) Quality Control Requirements;
  - (vi) Tender Form furnished by the supplier;
  - (vii) Price Schedule(s) furnished by the supplier in its tender;
  - (viii) Manufacturers' Authorisation Form (if applicable for this tender);
  - (ix) Purchaser's Notification of Award

**Note:** The words and expressions used in this contract shall have the same meanings as are respectively assigned to them in the conditions of contract referred to above. Further, the definitions and abbreviations incorporated under clause 1 of Section II – 'General Instructions to Tenderers' of the Purchaser's TE document shall also apply to this contract.

5. Some terms, conditions, stipulations etc. out of the above-referred documents are reproduced below for ready reference:
  - (i) Brief particulars of the goods and services which shall be supplied/ provided by the supplier are as under:

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

Schedule No.	Brief description of goods/services	Accounting unit	Quantity to be supplied	Unit Price	Total price	Terms of delivery

Any other additional services (if applicable) and cost thereof: \_\_\_\_\_

Total value (in figure) \_\_\_\_\_ (In words) \_\_\_\_\_

1. Delivery schedule
  - (i) Details of Performance Security
  - (ii) Quality Control
    - (a) Mode(s), stage(s) and place(s) of conducting inspections and tests.
    - (b) Designation and address of purchaser's inspecting officer
  - (iii) Destination and despatch instructions
  - (iv) Consignee, including port consignee, if any
2. Warranty clause
3. Payment terms
4. Paying authority

\_\_\_\_\_  
**(Signature, name and address of CONSIGNEE)**

**For and on behalf of** \_\_\_\_\_

Received and accepted this contract

\_\_\_\_\_  
(Signature, name and address of the supplier's executive duly authorised to sign on behalf of the supplier)


For and on behalf of \_\_\_\_\_

(Name and address of the supplier)

\_\_\_\_\_  
(Seal of the supplier)

Date: \_\_\_\_\_

Place: \_\_\_\_\_

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**SECTION – XVI  
CONTRACT FORM – B  
CONTRACT FORM FOR ANNUAL MAINTENANCE CONTRACT**

**Annual Maintenance Contract No.** \_\_\_\_\_ **dated** \_\_\_\_\_

Between

\_\_\_\_\_

\_\_\_\_\_

**CONSIGNEE**

And

\_\_\_\_\_

\_\_\_\_\_

(Name & Address of the Supplier)

**Ref: Contract No** \_\_\_\_\_ **dated** \_\_\_\_\_ **(Contract No. & date of Contract for supply, installation, commissioning, validation, handing over, Trial run, Training of operators & warranty of goods)**


In continuation to the above referred contract

2. The Contract of Annual Maintenance is hereby concluded as under: -

1	2	3	4		5
Schedule No.	Brief description of goods	Quantity. (No.)	Annual Maintenance Contract Cost for Each Unit year wise*.		Total Annual Maintenance Contract Cost for 2 Years [3 x (4A+4B)]
			1 <sup>st</sup>	2 <sup>nd</sup>	
			A	B	

Total value (in figure) \_\_\_\_\_ (In words) \_\_\_\_\_

- b) The AMC commence from the date of expiry of all obligations under Warranty i.e. from \_\_\_\_\_ (date of expiry of Warranty) and will expire on \_\_\_\_\_ (date of expiry of AMC)
- c) The cost of Annual Maintenance Contract (AMC) which includes preventive maintenance, labour and spares, after satisfactory completion of Warranty period may be quoted for next 2 years as contained in the above referred contract on yearly basis for complete equipment and Turnkey (if any).
- d) There will be 98% uptime warranty during AMC period on 24 (hrs) X 7 (days) X 365 (days) basis, with penalty, to extend AMC period by double the downtime period.
- e) During AMC period, the supplier shall visit at each consignee's site for preventive maintenance including testing and calibration as per the manufacturer's service/ technical/ operational manual. The supplier shall visit each consignee site as recommended in the manufacturer's manual, but at

<b>Client :</b> 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>  <b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>		<b>Revision : 00  Date : 2014.11.13</b>

least once in 3 months commencing from the date of the successful completion of warranty period for preventive maintenance of the goods.

- f) All software updates should be provided free of cost during AMC.
- g) **Payment terms:** The payment of AMC will be made against the bills raised to the consignee by the supplier on six monthly basis after satisfactory completion of said period, duly certified by the HOD concerned.

\_\_\_\_\_ (name of the consignee)

\_\_\_\_\_  
**(Signature, name and address of Consignee)**

**For and on behalf of** \_\_\_\_\_

Received and accepted this contract


\_\_\_\_\_  
(Signature, name and address of the supplier's executive  
duly authorised to sign on behalf of the supplier)

For and on behalf of \_\_\_\_\_  
(Name and address of the supplier)

\_\_\_\_\_  
(Seal of the supplier)

Date: \_\_\_\_\_


Place: \_\_\_\_\_

<b>Client :</b> 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00  Date : 2014.11.13</b>

**SECTION – XVII**  
**PROFORMA OF CONSIGNEE RECEIPT CERTIFICATE**  
**(To be given by consignee’s authorized representative)**

The following store(s) has/have been received in good condition:

- 1) Contract No. & date : \_\_\_\_\_
- 2) Supplier’s Name : \_\_\_\_\_
- 3) Consignee’s Name & Address with telephone No. & Fax No. : \_\_\_\_\_
- 4) Name of the item supplied : \_\_\_\_\_
- 5) Quantity Supplied : \_\_\_\_\_
- 6) Date of Receipt by the Consignee : \_\_\_\_\_
- 7) Name and designation of Authorized Representative of Consignee : \_\_\_\_\_
- 8) Signature of Authorized Representative of Consignee with date : \_\_\_\_\_
- 9) Seal of the Consignee : \_\_\_\_\_

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>  <b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	nne pharmaplan®
<b>Project No : 120310</b>		<b>Revision : 00 Date : 2014.11.13</b>

**SECTION – XVIII**  
**Proforma of Final Acceptance Certificate by the Consignee**

**No** \_\_\_\_\_

**Date** \_\_\_\_\_

**To**  
**M/s** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Subject: Certificate of commissioning of equipment/plant.**

This is to certify that the equipment(s)/plant(s) as detailed below has/have been received in good conditions along with all the standard and special accessories and a set of spares (subject to remarks in Para no.02) in accordance with the contract/technical specifications. The same has been installed and commissioned.

- (a) Contract No \_\_\_\_\_ dated \_\_\_\_\_
- (b) Description of the equipment(s)/plants: \_\_\_\_\_
- (c) Equipment(s)/ plant(s) nos.: \_\_\_\_\_
- (d) Quantity: \_\_\_\_\_
- (e) Bill of Loading/Air Way Bill/Railway Receipt/ Goods Consignment Note no \_\_\_\_\_ dated \_\_\_\_\_
- (f) Name of the vessel/Transporter: \_\_\_\_\_
- (g) Name of the Consignee: \_\_\_\_\_
- (h) Date of commissioning and proving test: \_\_\_\_\_

**Details of accessories/spares not yet supplied and recoveries to be made on that account.**


Sl. No.	Description of Item	Quantity	Amount to be recovered

The proving test has been done to our entire satisfaction and operators have been trained to operate the equipment(s)/plant(s).

The supplier has fulfilled its contractual obligations satisfactorily ## or

The supplier has failed to fulfill its contractual obligations with regard to the following:

- He has not adhered to the time schedule specified in the contract in dispatching the documents/drawings pursuant to 'Technical Specifications'.
- He has not supervised the commissioning of the equipment(s)/plant(s) in time, i.e. within the period specified in the contract from date of intimation by the Purchaser/Consignee in respect of the

Client : 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>  <b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	nne pharmaplan®
<b>Project No : 120310</b>		<b>Revision : 00</b> <b>Date : 2014.11.13</b>

installation of the equipment(s)/plant(s).

- The supplier as specified in the contract has not done training of personnel.

The extent of delay for each of the activities to be performed by the supplier in terms of the contract is:

The amount of recovery on account of non-supply of accessories and spares is given under Para no.02.

The amount of recovery on account of failure of the supplier to meet his contractual obligations is \_\_\_\_\_ (here indicate the amount).

Signature

Name

Designation with stamp

**## Explanatory notes for filling up the certificate:**


**He has adhered to the time schedule specified in the contract in dispatching the documents/drawings pursuant to 'Technical Specification'.**

**He has supervised the commissioning of the equipment(s)/plant(s) in time, i.e. within the time specified in the contract from date of intimation by the Purchaser/Consignee in respect of the installation of the equipment(s)/plant(s).**

**Training of personnel has been done by the supplier as specified in the contract**

**In the event of documents/drawings having not been supplied or installation and commissioning of the equipment(s)/plant(s) having been delayed on account of the supplier, the extent of delay should always be mentioned in clear terms.**




<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>  <b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>		<b>Revision : 00 Date : 2014.11.13</b>


**SECTION – XIX  
CHECKLIST**

**NAME OF TENDERER:  
NAME OF MANUFACTURER:**

SI No.	Activity	Yes/ No/ NA	Page No. in the TENDER document	Remarks
1. a.	Have you enclosed EMD of required amount for the quoted schedules?			
b.	In case EMD is furnished in the form of Bank Guarantee, has it been furnished as per Section XIII?			
c.	In case Bank Guarantee is furnished, have you kept its validity of 165 days from Technical Bid Opening date as per clause 18 of GIT?			
2. a.	Have you enclosed duly filled Tender Form as per format in Section X?			
b.	Have you enclosed Power of Attorney in favour of the signatory?			
3.	Are you a SSI unit, if yes have you enclosed certificate of registration issued by Directorate of Industries/NSIC			
4. a.	Have you enclosed clause-by-clause technical compliance statement for the quoted goods vis-à-vis the Technical specifications?			
b.	In case of Technical deviations in the compliance statement, have you identified and marked the deviations?			
5. a.	Have you submitted satisfactory performance certificate as per the Proforma for performance statement in Sec. IX of TE document in respect of all orders?			
b.	Have you submitted copy of the order(s) and end user certificate?			
6.	Have you submitted manufacturer's authorization as per Section XIV?			
7.	Have you submitted prices of goods, turnkey (if any), AMC etc. in the Price Schedule as per Section XI?			
8.	Have you kept validity of 120 days from the Technical bid Opening date as per the TE document?			

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

SI No.	Activity	Yes/ No/ NA	Page No. in the TENDER document	Remarks
9. a.	In case of Indian Tenderer, have you furnished Income Tax Account No. as allotted by the Income Tax Department of Government of India?			
b.	In case of Foreign Tenderer, have you furnished Income Tax Account No. of your Indian Agent as allotted by the Income Tax Department of Government of India?			
10.	Have you intimated the name and full address of your Banker (s) along with your Account Number			
11.	Have you fully accepted payment terms as per TE document?			
12.	Have you fully accepted delivery period as per TE document?			
13.	Have you submitted the certificate of origin			
14.	Have you accepted the warranty as per TE document?			
15.	Have you accepted terms and conditions of TE document?			
16.	Have you furnished documents establishing your eligibility & qualification criteria as per TE documents?			
17	Have you furnished Annual Report (Balance Sheet and Profit & Loss Account) for last three years prior to the date of Tender opening?			
18	Have you signed and sealed the Integrity Pact as per section XXI of the tender			
19	Have you enclosed the DD/Bankers cheque for the tender fee?			

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>  <b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>		<b>Revision : 00</b> <b>Date : 2014.11.13</b>

N.B.

1. All pages of the Tender should be page numbered and indexed.
2. The Tenderer may go through the checklist and ensure that all the documents/confirmations listed above are enclosed in the tender and no column is left blank. If any column is not applicable, it may be filled up as NA.
3. It is the responsibility of tendered to go through the TE document to ensure furnishing all required documents in addition to above, if any.

---


**(Signature with date)**

---

**(Full name, designation & address of the person duly authorised sign on behalf of the  
Tenderer)  
For and on behalf of**

---

**(Name, address and stamp of the tendering firm)**



<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**Section – XX**

**Consignee**

**All Goods shall be delivered at**

**“INTEGRATED VACCINES COMPLEX,  
CHENGALPATTU - 603001, TAMILNADU, INDIA”**

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

**SECTION – XXI**

To be signed by the bidder and same signatory competent/authorized to sign the relevant contract of behalf of HLL Biotech Limited

**INTEGRITY AGREEMENT**

This Integrity Agreement is made at ..... on this ..... Day of.....20.....

**BETWEEN**

President of India represented through Chief Executive Officer, HLL Biotech Limited (Hereinafter referred as the “Principal/Owner”, which expression shall unless repugnant to the meaning or context hereof include its successors and permitted assigns.

**AND**

..... through .....(Hereinafter referred to as the “**Bidder/Contractor**” and which expression shall unless repugnant to the meaning or context hereof include its successors and permitted assigns).

**Preamble**


WHEREAS the Principal / owner has floated the Tender (NIT No.....) (hereinafter referred to as “**Tender/Bid**”) and intends to award, under laid down organizational procedure, contract for ..... Hereinafter referred to as the “**Contract**”

AND WHEREAS the Principal /Owner values full compliance with all relevant laws of the land, rules, regulations, economic use of resources and of fairness/transparency in its relation with its Bidder(s) and Contractor(s).

AND WHEREAS to meet the purpose aforesaid both the parties have agreed to enter into this Integrity Agreement (hereinafter referred to as “**Integrity Pact**” or “**Pact**”), the terms and conditions of which shall also be read as integral part and parcel of the Tender Bid documents and Contract between the parties. NOW, THEREFORE, in consideration of mutual covenants’ contained in this Pact, the parties hereby agree as follows and this Pact witnesses as under:

**Article 1: Commitment of the Principal /Owner**



- 1) The Principal /Owner commits itself to take all measures necessary to prevent corruption and to observe the following principles.
  - (a) No employee of the Principal/Owner, personally or through any of his/her family members, will in connection with the Tender, or the execution of the Contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.
  - (b) The Principal/Owner will, during the Tender process, treat all Bidder(s) with equity and reason. The Principal/owner will, in particular, before and during the Tender process, provide to all Bidder(s) the same information and will not provide to any Bidder(s) confidential / additional information through which the Bidder (s) could obtain an advantage in relation to the Tender process or the Contract execution.
  - (c) The Principal /Owner shall Endeavour to exclude from the Tender process any person, whose conduct in the past has been of biased nature.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

- 2) If the Principal/Owner obtains information on the conduct of any of its employees which is a criminal offence under the Indian Penal code (IPC)/Prevention of Corruption Act, 1988 (PC Act) or is in violation of the principles herein mentioned or if there be a substantive suspicion in this regard, the Principal/Owner will inform the Chief Vigilance Officer and in addition can also initiate disciplinary actions as per its internal laid down policies and procedures.

**Article 2: Commitment of the Bidder(s) / Contractor(s)**

- 1) It is required that each Bidder/Contractor(including their respective officers, employees and agents) adhere to the highest ethical standards, and report to the Government/Department all suspected acts of **fraud or corruption or Coercion or Collusion** of which it has knowledge or becomes aware, during the tendering process and throughout the negotiation or award of a contract.
- 2) The Bidder(s)/Contractor(s) commit himself to take all measures necessary to prevent corruption. He commits himself to observe the following principles during his participation in the Tender process and during the Contract execution.
  - (a) The Bidder(s)/Contractor(s) will not, directly or through any other person or firm, offer, promise or give to any of the Principal/owner's employees involved in the Tender process or execution of the Contract or to any third person any material or other benefit which he/she which he/she is not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the Tender process or during the execution of the Contract.
  - (b) The Bidder(s) will not enter with other Bidder(s) into any undisclosed agreement or understanding, whether formal or informal. This applies in particular to prices, specifications, certification, subsidiary contracts, submission or non-submission of bids or any other actions to restrict competitiveness or to cartelize in the bidding process.
  - (c) The Bidder(s)/Contractor(s) will not commit any offence under the relevant IPC/PC Act. Further the Bidder(s) /Contractor(s) will not use improperly, (for the purpose of competition or personal gain).or pass on to others, any information or documents provided by the Principal/Owner as part of the business relationship, regarding plans, technical proposals and business details, including and business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically.
  - (d) The Bidder (s) /Contractor (s) of foreign origin shall disclose the names and addresses of agents/representatives in India, if any Similarly Bidder(s)/Contractor(s) of Indian Nationality shall disclose names and addresses of foreign agents/representatives, if any. Either the Indian agent on behalf of the foreign principal or the foreign principal directly could bid in a tender but not both. Further, in cases where an agent participate in a tender on behalf of one manufacturer, he shall not be allowed to quote on behalf of another manufacturer along with the first manufacturer in a subsequent/parallel tender for the same item.
  - (e) The Bidder (s)/Contractor (s) will , when presenting his bid, disclose (with each tender as per proforma unclosed) any and all payments he has made, is committed to or intends to make to agents, brokers or any other intermediaries in connection with the award of the Contract.
- 3) The Bidder(s) /Contractor(s) will not instigate third persons to commit offences outlined above or be an accessory to such offences.
- 4) The Bidder (s)/contractor(s) will not, directly or through any other person or firm indulge in fraudulent practice means a willful misrepresentation or omission of facts or submission of fake/forged documents in order to induce public official to act in reliance thereof, with the purpose of obtaining unjust advantage by or causing damage to justified interest of others and /or to influence the procurement process to the detriment of the Government interests.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

- 5) The Bidder(s)/Contractor(s) will not, directly or through any other person or firm use Coercive Practices (Means the act of obtaining something, compelling an action or influencing a decision through intimidation, threat or the use of force directly or indirectly, where potential or actual injury may befall upon a person, his/her reputation or property to influence their participation in the tendering process).



### **Article 3: Consequences of Breach**

Without prejudice to any rights that may be available to the Principal/Owner under law or the Contract or its established policies and laid down procedures, the Principal/Owner shall have the following rights in case of breach of this integrity Pact by the Bidder (s)/Contractor(s) and the Bidder(s)/Contractor(s) accepts and undertakes to respect and uphold the Principal /Owner's absolute right:

- 1) If the Bidders) / Contractor(s), either before award or during execution of Contract has committed a transgression through a violation of Article 2 above or in any other form, such as to put his reliability or credibility in question, the Principal/owner after giving 14 days notice to the contractor shall have powers to disqualify the Bidder (s)/Contractor(s) from the Tender process or terminate/determine the Contract, if already executed or exclude the Bidder/Contractor from future contract award processes. The imposition and duration of the exclusion will be determined by the severity of transgression and determined by the Principal/owner. **Such exclusion may be forever or for a limited period as decided by the Principal/owner.**
- 2) **Forfeiture of EMD/performance Guarantee/Security Deposit:** If the Principal/owner has disqualified the Bidder(s) from the Tender process prior to the award of the Contract or terminated/determined the Contract or has accrued the right to terminate/determine the Contract according to Article 3(1), the Principal /Owner apart from exercising any legal rights that may have accrued to the Principal/Owner, may in its considered opinion forfeit the entire amount of Earnest Money Deposit, Performance Guarantee and security Deposit, Performance Guarantee and security Deposit of the Bidder/Contractor.
- 3) **Criminal Liability:** If the Principal/Owner obtains knowledge of conduct of a Bidder or Contractor, or of and employee or a representative or an associate of a Bidder or Contractor which constitutes corruption within the meaning of Indian Penal code (IPC)/Prevention of corruption Act, or if the Principal/owner has substantive suspicion in this regard, the Principal/owner will inform the same to law enforcing agencies for further. Investigation.

### **Article 4- Previous Transgression**

- 1) The Bidder declares that no previous transgressions occurred in the last 5 years with any other Company in any country confirming to the anticorruption approach or with Central Government or State Government or any other Central/State Public sector Enterprises in India that could justify his exclusion from the Tender process.
- 2) If the Bidder makes incorrect statement on this subject, he can be disqualified from the Tender process or action can be taken for banning of business dealings/ holiday listing of the Bidder/Contractor as deemed fit by the Principal/owner.
- 3) If the Bidder/Contractor can prove that he has resorted / recouped the damage caused by him and has installed a suitable corruption prevention system, the Principal/owner may, at its own discretion, revoke the exclusion prematurely.

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**Article 5- Equal Treatment of all Bidders/Contractors/Subcontractors**

- 1) The Bidder(s) /Contractor(s) undertake(s) to demand from all subcontractors a commitment in conformity with this Integrity Pact. The Bidder/Contractor shall be responsible for any violation(s) of the principles laid down in this agreement /pact by any of its Sub-contractors/sub-vendors.
- 2) The Principal/owner will enter into Pacts on identical terms as this one with all Bidders and Contractors.

**Article 6- Duration of the Pact**

This Pact begins when both the parties have legally signed it. It expires for the Contractor/Vendor 12 months after the completion of work under the contract or till the continuation of defect Liability period, whichever is more and for all other bidders, till the Contract has been awarded.

If any claim is made/lodged during the time, the same shall be binding and continue to be valid despite the lapse of this Pacts as specified above, unless it is discharged /determined by the competent authority, HLL Biotech Limited.


**Article 7- other Provisions**

- 1) This Pact is subject to Indian Law., place of performance and jurisdiction is the Head quarters of HLL Biotech Limited of the Principal/Owner, who has floated the Tender.
- 2) Changes and supplements need to be made in writing. Side agreements have not been made.
- 3) If the Contractor is a partnership or a consortium, this Pact must be signed by all the partners or by one or more partner holding power of attorney signed by all the partners or by one or more partner holding power of attorney signed by all partners and consortium members. In case of a company, the Pact must be signed by a representative duly authorized by board resolution.
- 4) Should one or several provisions of this Pact turn out to be invalid; the remainder of this Pact remains valid. In this case, the parties will strive to come to an agreement to their original intensions.
- 5) It is agreed term and condition that any dispute or difference arising between the parties with regard to the terms of this Integrity Agreement/pact, any action taken by the Owner/Principal in accordance with this **Integrity Agreement/Pact or interpretation thereof shall not be subject to arbitration.**

**Article 8- LEGAL AND PRIOR RIGHTS:**

All rights and remedies of the parties hereto shall be in addition to all the other legal rights and remedies belonging to such parties under the Contract and /or law and the same shall be deemed to be cumulative and not alternative to such legal rights and remedies aforesaid. For the sake of brevity, both the Parties agree that this Integrity Pact will have precedence over the Tender /Contact documents with regard any of the provisions covered under this Integrity Pact.



<b>Client :</b> 	<b>TENDER DOCUMENT FOR  SUPPLY, INSTALLATION, COMMISSIONING &amp;  VALIDATION OF VIAL WASHING MACHINE WITH  DEPYROGENATING TUNNEL AND VIAL SEALING  MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00  Date : 2014.11.13</b>

IN WITNESS WHERE OF the parties have signed and executed this Integrity Pact at the place and date first above mentioned in the presence of following witnesses:

.....  
(For and on behalf of Principal/owner)

.....  
(For and on behalf of Bidder/Contractor)

**WITNESSES:**

1.


(Signature, Name & address)

2.

(Signature, Name & address)


Place:

Date:

<b>Client :</b> 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	<b>nne pharmaplan®</b>
<b>Project No : 120310</b>	<b>DOCUMENT NO : NPI-120310-EQP-S1-TD-09</b>	<b>Revision : 00 Date : 2014.11.13</b>

**Section XXII**


**Deleted**

Client : 	<b>TENDER DOCUMENT FOR SUPPLY, INSTALLATION, COMMISSIONING &amp; VALIDATION OF VIAL WASHING MACHINE WITH DEPYROGENATING TUNNEL AND VIAL SEALING MACHINES</b>	nne pharmaplan®
Project No : 120310	DOCUMENT NO : NPI-120310-EQP-S1-TD-09	Revision : 00 Date : 2014.11.13

### Section XXIII

#### SCHEDULE OF FISCAL ASPECTS

Sr. No.	Particulars	Description
1.	Submission of completed Tender	09-12-2014 at 15:00 Hrs
2.	Opening of Technical Bid	09-12-2014 at 15:30 Hrs
3.	Delivery	7 months from the date of issuance of LOA
4.	Installation, commissioning and validation	2 (two) months from the delivery of the equipment at site.
5.	Advance	10% of the contract value against Bank Guarantee equivalent to 110% of the advance amount and submission of Security Deposit/ Performance Security of 5% of contract value from a Scheduled Commercial Bank. In case of Foreign tenderer, the bank guarantee shall be routed through a nationalized Indian Bank
6.	Payment terms	As mentioned in GCC: Clause. 21
7.	Liquidated damages/per week	0.5% per week inclusive of Sundays & Holidays upto a maximum of 5% of Contract Value
8.	Warranty Period	12 (Twelve) months from the date of Completion.
9.	Earnest Money Deposit	Rs. 18,00,000/-
10.	Refund of Earnest Money Deposit to unsuccessful bidders	On award of contract to successful bidder
11.	Insurance	On account of Supplier
12.	B.G/ DD to be in favor of	HLL Biotech Ltd., Chennai
13.	All queries / communication to be addressed to	The Chief Executive Officer HLL Biotech Limited, Ticel Biopark Campus (Module no. 013-015), CSIR Road, Taramani, Chennai- 600 113 Email: <a href="mailto:sureshs@hllbiotech.com">mailto: sureshs@hllbiotech.com</a> , ceo@hllbiotech.com, Contact No: 044 22544956/949 , Fax – 044 22540101
14.	Pre-bid Meeting	<b>Venue:</b> HLL Biotech Limited, Ticel Biopark Campus (Module no. 013 - 015), CSIR Road, Taramani, Chennai- 600 113 <b>Date and Time: 20-11-2014 at 10:30 Hrs</b>
<b>(Contractor)</b>		<b>(Employer)</b>


nne pharmaplan	<b>User Requirement Specifications</b>			 <small>HLL BIOTECH LIMITED          Subsidiary of HLL Group Limited          P. Government of India Company</small>	
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel			
	Identification #:	-	Document No:		URS/VWD 01
	Effective Date	03-11-2014	Revision No:		02

## User Requirement Specifications Vial Washing Machine With Depyrogenation Tunnel

Block Code	Block Name	Identification #	Capacity	Qty [Nos]
F1	Viral Vaccine Formulation- Rabies	F1-VWD 01	200 Vials/Minute	1
F1	Viral Vaccine Formulation- Measles	F1-VWD 02	200 Vials/Minute	1
F2	Bacterial Vaccine Formulation	F2-VWD 01	200 Vials/Minute	1

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**


<b>nne pharma plan</b>	<b>User Requirement Specifications</b>			 <small>HLL BIOTECH LIMITED                  Subsidiary of HLL Life Sciences Limited                  (A Government of India Enterprise)</small>	
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel			
	Identification #:	-	Document No:		URS/VWD 01
	Effective Date	03-11-2014	Revision No:		02

**URS Annexure List**

URS Annex No.	Detail
1	Layout showing location of the installation of the Vial washing machine with Depyrogenation tunnel
2	List of components and make
3	List of Critical Spares
4	Specifications of customized vials

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**


HLL pharmaplan	<b>User Requirement Specifications</b>				
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VWD 01
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>		02

**Table of Contents**

<b>1.0</b>	<b>APPROVAL SIGNATURE.....</b>	<b>4</b>
<b>2.0</b>	<b>EQUIPMENT DESCRIPTION .....</b>	<b>5</b>
<b>3.0</b>	<b>PROCESS DESCRIPTION.....</b>	<b>7</b>
3.1	INPUT & CHARGING METHOD .....	7
3.2	BRIEF PROCESS STEPS.....	7
3.3	OUTPUT & DISCHARGING METHOD .....	9
<b>4.0</b>	<b>PRODUCTIVITY REQUIREMENT.....</b>	<b>9</b>
4.1	DESIRED/ SUGGESTED CAPACITY .....	9
4.2	STANDARD BATCH SIZE .....	10
4.3	CHANGE OVER TIME (IF APPLICABLE).....	10
4.4	OTHER PRODUCTIVITY REQUIREMENT .....	10
<b>5.0</b>	<b>CONTAINMENT .....</b>	<b>10</b>
<b>6.0</b>	<b>GMP REQUIREMENTS.....</b>	<b>10</b>
6.1	PROCESS CONTROL .....	10
6.2	FAILURE MODE DETECTION AND ALARMS .....	10
6.3	IN -PROCESS CONTROL .....	11
6.4	LEVEL OF INSTRUMENTATION.....	11
6.5	BATCH DATA DISPLAY AND RECORD PRINTING .....	13
6.6	GMP REQUIREMENTS (OTHERS).....	13
6.7	SPECIFIC REQUIREMENTS.....	14
<b>7.0</b>	<b>CONSTRAINTS .....</b>	<b>15</b>
7.1	EQUIPMENT LOCATION AND AVAILABLE SPACE .....	15
7.2	AVAILABLE UTILITY.....	16
<b>8.0</b>	<b>ABBREVIATION.....</b>	<b>17</b>
<b>9.0</b>	<b>REVISION INDEX.....</b>	<b>17</b>

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

nne pharmaplan	<b>User Requirement Specifications</b>				
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VWD 01
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>		02

**1.0 APPROVAL SIGNATURE**



This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccines Complex, Chengalpattu, Chennai" (project number: 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be reviewed by HBL user/s and project/ engineering team, approved by team lead of user department and QA and authorized by the appropriate Project Authority.

<b>NNE Pharmaplan India Limited</b>			
Name	Designation	Signature	Date
<b>Prepared by</b>			
Mr. Yogesha M J	Process Engineer	<i>Yogesha M.J.</i>	29.10.2014
<b>Checked by</b>			
Mr. Sridhar Babu K	Senior Process Engineer	<i>K Sridhar Babu</i>	29.10.2014
<b>Approved by</b>			
Mr. Vikas Katial	GM & Head-COC Vaccines	<i>Vikas Katial</i>	29.10.2014

<b>HLL Biotech Limited</b>			
Name	Designation	Signature	Date
<b>Reviewed by</b>			
B.SATHISH	M-Formulation (Viral Vaccine)	<i>B.Sathish</i>	30.10.2014
K.RADHAKRISHNAN	DM PRODUCTION	<i>K.Radhakrishnan</i>	30.10.2014
G.RAMESH	DM (Bacterial vaccine formulation)	<i>G.Ramesh</i>	30.10.2014
VIGNESHKARAN.T	AM-PROJECTS	<i>Vigneshkaran.T</i>	30.10.2014
<b>Approved By</b>			
<i>Dr. Jyothsna Venkatesh</i>	Project Head (P.V)	<i>Dr. Jyothsna Venkatesh</i>	31/10/14
<i>J.R. KUMARAN</i>	DVP-Production	<i>J.R. Kumaran</i>	30.10.2014
G.NARASIMHA REDDY	Sr. Manager	<i>G.Narasimha Reddy</i>	30.10.2014
<i>R. JYOTHA BABU</i>	DM - QC & QA	<i>R. Jyotha Babu</i>	31.10.2014
<b>Authorized by</b>			
RAMAN.K.R	CEO	<i>Raman.K.R</i>	03.11.2014

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

	User Requirement Specifications				
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel			
	Identification #:	-	Document No:	URS/VWD 01	
	Effective Date	03-11-2014	Revision No:	02	

**2.0 EQUIPMENT DESCRIPTION**

The vial washing machine and the Depyrogenation tunnel should be made in combination with proper synchronization to each other. The vial washing machine should have a speed of 200 vials/min (In feed to filling machine should not be less than 200 vials /minute).

The machine should consist of following parts in order to run operation smoothly.

S. No.	Description	Purpose
<b>Vial Washing Machine</b>		
1	In feed turntable	Feeding the vials to the turntable with conveyor belt from de-cartooning room should be provided. The vials will be unscrambled and singled to the washing station.
2	Transport system	Transporting the pre washed vials to the washing unit.
3	Recirculation unit	Recirculating the WFI drained from final rinse of vials to be used for initial rinsing of vials
4	Washing Cycle	Washing the vials with WFI/Recirculated WFI.
5	Vapor Exhaust unit	Vapor Exhaust from the washing unit.
6	Out feed	Feeding the vials into the Tunnel
<b>Depyrogenation tunnel</b>		
1	Conveyor	Vials to be transported through appropriate transport system. [An auto pusher system to push the overload of vials in the tunnel should be provided.] MOC:-SS 316L
2	Drying zone with HEPA	For drying the washed vials with HEPA filtered air
3	Depyrogenation zone with HEPA	For Depyrogenation the vials with circulation of HEPA filtered air (hot air)
4	Cooling /stabilization zone with HEPA	For cooling the vials with circulation of HEPA filtered air to bring the temperature to ambient

Machine should have all operation in automatic mode. All the regulatory requirements should be followed. The loading of the vials to the infeed bay should be done by conveyor. The vial should be transferred to the washing unit in a group by the transport system. The vials in the washing unit should be washed from the inside as well as from outside. The washing cycle should include washing with recirculated WFI and WFI with intermediate sterile compressed air drying. The equipment should reduce contaminations and particulate matter. It should help to reduce the amount of endotoxins by the use of fresh WFI at the last rinse. A combination of at least six washing and drying cycle should take place in the washing station. The washed vials should be transferred to the tunnel by the conveyor system.


The tunnel should be designed to produce the Depyrogenation condition by achieving a temperature in the range of 300-350°C. The process should be capable of doing a 6 log reduction for viable germs and ≥ 3 log for endotoxins.

The temperature of vials at the outlet of cooling zone should be 22°C ±2°C for all machines. The system should maintain a uniform temperature inside the tunnel. The wire mesh conveyor should transport the vials from the in feed to the filling area through the drying, Depyrogenation and cooling zone.



**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

<b>nne pharmanan</b>	<b>User Requirement Specifications</b>				
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VWD 01
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>		02

**All points of the IRS except the below mentioned would be applicable for the equipment**

- 4.1.10, 4.1.11, 4.1.13, 4.1.17
- ANSI/NSF 49-2008,

**Note:**

I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. In case of any deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
III.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options become necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or an information from the vendor, the answer / information should be stated in the "REMARKS" column.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design.
VIII.	<p>Special Instruction</p> <p>a. If no comments against any specification should be considered as "NO" and</p> <p>b. If there is no reply / comments against the complete URS by the vendor then it should be treated as unresponsive / technically non compliant and rejected.</p>
IX.	All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HBL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI-120310-IRS-S1-01
XII.	Refer Tender document with URS; NPI-120310-EQP-S1-TD-09

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

HBL HLL BIOTECH LIMITED VIAL WASHING MACHINE @ CHENGALPATTU	User Requirement Specifications			
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel		
	Identification #:	-	Document No:	URS/VWD 01
	Effective Date	03-11-2014	Revision No:	02

--	--	--	--	--

Specifications				Remarks
----------------	--	--	--	---------

<b>3.0</b>	<b>PROCESS DESCRIPTION</b>			
------------	----------------------------	--	--	--

<b>3.1</b>	<b>Input &amp; Charging method</b>			
------------	------------------------------------	--	--	--

Unwashed vials: Vials should be loaded on to the tray in the vial loading area and then transferred to the infeed turntable of the washing machine through the transport conveyor.

<b>3.2</b>	<b>Brief Process Steps</b>			
------------	----------------------------	--	--	--

<b>3.2.1</b>	<b>Vial Washing Machine</b>			
--------------	-----------------------------	--	--	--

The rotary washing machines should be capable to accommodate multiple cleaning stations

- Station 1: Recirculated WFI 1 x interior / 1 x exterior
- Station 2: Compressed air 1 x interior
- Station 3: Purified water 1 x interior
- Station 4: Compressed air 1 x interior
- Station 5: Fresh WFI 1 x interior
- Station 6: Compressed air 2 x interior / 1 x exterior

**a) Re-circulated WFI:** Re-circulated WFI is used for rinsing of vials (Station 1) (internal). The vial washing machine should have all arrangement for recirculation of water. The recirculated water should pass through a pre-filter 5-micron filter. The vendor should inform the exact arrangement of recirculation system in its technical offer. Fresh WFI to be considered as makeup of the tank.

**b) Purified water:** Purified water is used in the initial rinsing of vials (Station 3) (internal and external). This purified should pass through 0.22 micron filter before entering into washing station and after washing, 100% of the rinse water (PW) should go to drain.

**c) Filtered Compressed air:** Filtered (0.22 micron) compressed air should be used to blow out water from the vials between different washing steps. Compressed air should also be used for removing water from the washed vials after final rinse to make it dry. (Station 2, 4 & 6).  
*Filter housing with integrity connector (suitable for connection with integrity test apparatus) should be vendor scope.*


**d) Fresh WFI:** Fresh WFI should be used as washing media in the vial washing machine. The vial washing machine should be suitable to collect Fresh WFI directly from the room supply valve of WFI distribution loop and it will be connected to the machine. Fresh WFI should be used for final rinse of vials. The interface location of connecting WFI line to the washing machine will be in the scope of the vendor.  
*Filter housing with 0.22 um Code 7 filter TC end along with distance piece & integrity connector (suitable for connection with integrity test apparatus) should be vendor scope*

**e) Transport System:** Appropriate system for holding of vials to be provided during transportation of vials to the washing station in upside down position for easy cleaning and after washing the vials will be re-inverted to their original position and transferred to the depyrogenation tunnel.

**f) Exhaust Module:** The machine should have exhaust module to extract water vapour generated during washing cycle from the washing machine. The module should consist of: Filter flange and flap to connect the blower which should be in the technical area. *The SS duct with drain and filter will be in user scope and suction motor will be in equipment*

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

nne pharma plan	User Requirement Specifications				
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel			
	Identification #:	-	Document No:		URS/VWD 01
	Effective Date	03-11-2014	Revision No:		02

*supplier scope.*

**3.2.2 Depyrogenation Tunnel**

**Performance requirements:**

- No decoloration of the vial
- No breakage of vial
- $\geq 3$  log reduction in endotoxin to be achieved.
- No change in the vial property.

**a) Washed vials from the washing machine:** The washed vials should be transported automatically to the infeed zone of the tunnel by a conveyor from washing machine.

**b) Air:** The room air should be sucked, supplied and re-circulated by the air handling unit of the tunnel. Final filtration is done by H 13 HEPA filter for hot zone and H 14 HEPA filter for drying and cooling zone respectively. The air should be delivered as unidirectional airflow from the laminar flow unit of the equipment. Vendor should inform the quantity of air intake from room.

**c) Infeed Zone:** Glass vials enters the tunnel belt and is spread to the width of the tunnel belt.

i. **Temperature:** Limited amount of heated air from the heat zone passes into the infeed zone to dry and rise the temperature of the glass vials, prior to their entry in to the heat zone. Drying zone should have suitable temperature monitoring, recording and display system in place.

ii. **Air Flow:** The glass vials are subjected to unidirectional air flow consistent across the width of the zone. Air velocity is maintained at +/-20% of the average airflow and is delivered from the HEPA air filter at a rate of 0.45 m/sec. Fresh air is provided to the inlet of the HEPA filter. Air is not re-circulated (once through). A differential pressure device with display and alarming capabilities will monitor the differential pressure between the internal zone and the outside room pressure. Exhaust air exits the Infeed Zone through a duct to the outside of the washer and sterilization room.

**d) Heat Zone:** The glass vials are transferred into the heat zone where the temperature is controlled to a level capable of providing the required thermal activation factor (FH). The FH provides the necessary temperature and time to ensure the required 6 log reduction for viable germs and  $\geq 3$  log for endotoxins.

i. **Temperature:** The temperature within the heat zone must be adjustable in 5°C increments from ambient to a maximum of 350°C. The temperature uniformity / distribution measured above the conveyor in the empty tunnel should be within the range of +/- 5°C (for temperature set above 250 °C) of the average, as measured in line across the belt (**As per USP-29 Chapter 1211**). The temperature uniformity / distribution measured inside of the vial should be within the range of +/- 5°C for tubing glass, as measured in line across the belt. A suitable temperature monitoring, recording and display system in place.

ii. **Air Flow:** The glass vials are subjected to laminar air flow consistent across the width of the zone. Air velocity is maintained at +/-20% of the average airflow, and is delivered from the HEPA air filter at a rate of 0.45 m/sec. Fresh air is provided to the inlet side of the HEPA filter. There is no exhaust in the heat zone. Fresh air is used to make-up air that is lost to the adjacent zones through the gates. A differential pressure device with display and alarming capabilities will monitor the differential pressure between the internal zone and the washer/tunnel room pressure.

**e) Cool Down Zone:** The glass vials are transferred to the cool down zone where the

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

HBL HLL BIOTECH LIMITED Quality Improvement & Customer Value Focus	User Requirement Specifications			
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel		
	Identification #:	-	Document No:	URS/VWD 01
	Effective Date	03-11-2014	Revision No:	02

glass vials are cooled down gradually to near ambient temperatures to prevent cracking of the glass vials, or damage to the outfeed guides due to high temperatures.

i. **Temperature Control:** The temperature of the glass vials must be cooled down to 22°C ±2°C for F1-VWD 01 , F1-VWD 02 and F2-VWD 01 at the exit of the tunnel. Cooling of the vials is accomplished using fresh HEPA filtered air. A suitable temperature monitoring, recording and display system in place.

ii. **Air Flow:** The glass vials are subjected to unidirectional air flow consistent across the width of the zone. Air velocity is maintained to +/-20% of the average airflow and passes through the HEPA air filter at a rate of 0.7meters/sec. Fresh air is provided to the inlet side of the HEPA filter through a roughing filter. Air/ Chilled water through the heat exchanger is recirculated with cooling battery. A differential pressure device with display, recording and alarming capabilities will monitor the differential pressure between the internal zone and the outside room pressure.

f) **Conveyor system:** Width of the tunnel belt should be as follows to match the in-feeder of the filling and stoppering machine;

F1-VWD 01	450 mm
F1-VWD 02	450 mm
F2-VWD 01	650 mm

**Note:**

- I. The out-feed of the tunnel should be at the height of ~900 mm to match with the in-feeder of the filling and stoppering machine.
- II. Dead plate design/drawing should be provided for each machine with all necessary specifications.

g) **Interface:** Vendor to consider the provision to integrate the 2 potential free contacts in each tunnel to communicate with the filling and stoppering machines. (Signal/Digital output will be provided by filling and stoppering machine vendor)

**3.3 Output & Discharging method**

The depyrogenated vials are transferred from the cooling zone to the filling machine by the conveyor movement.

**4.0 PRODUCTIVITY REQUIREMENT**

**4.1 Desired/ suggested capacity**

**Capacity:**

The washing machine and depyrogenation tunnel should be suitable to produce washed and sterilized vials at the specified rate[minimum 200vials/minute] to the filling and stoppering machine based on the following vial sizes

F1-VWD 01	ISO 2R	<b>As per DIN: ISO 8362-1 standard</b>	200 Vials/min
	ISO 4R		200 Vials/min
F1-VWD 02	ISO 4R		200 Vials/min
	ISO 2R		200 Vials/min
F2-VWD 01	ISO 6R		200 Vials/min
	<b>Customized vial</b>		<b>To be specified by vendor</b>

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

HBL HLL BIOTECH LIMITED Chennai, Tamil Nadu, India	<b>User Requirement Specifications</b>		
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel	
	<b>Identification #:</b>	-	<b>Document No:</b> URS/VWD 01
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b> 02

*\*Refer the URS Annexure-4 for the specifications of the customized vials*  
**Efficiency:**

- Washing machine: Must be greater than 98% with respect to quality aspects.
- Depyrogenation: 100% with respect to quality aspects.

**4.2 Standard batch size**

The machine should be capable to wash, sterilize and feed the vials at the rate of 200 vials / minute to the filling machine and should be capable of running on a continuous basis.  
 The standard batch size will vary from 40,000 vials/batch to 1,00,000 vials/batch.

**4.3 Change over time (if applicable)**

Change part replacement should not take more than 30 minutes.

**4.4 Other productivity requirement**

- 4.4.1 Vendor to give information on change over time.
- 4.4.2 The equipment should be able to run for 24 hours.

**5.0 CONTAINMENT**

Not Applicable

**6.0 GMP REQUIREMENTS**

**6.1 Process control**

**6.1.1 Washing Machine**

Equipment to have suitable control system to verify and control the process.

**6.1.2 Depyrogenation Tunnel**

Equipment to have suitable control system to verify and control the process.

**6.2 Failure mode detection and Alarms**

**6.2.1 Washing Machine**

A. Equipment should be provided with audio visual alarms and the equipment must restart with manual intervention.


- a) Main drive motor overload, Turntable motor overload, Pump overload.
- b) In feed/ out feed empty.
- c) In feed jamming and maximum out feed condition reached at the inlet of tunnel.
- d) Toppled vials, machine should stop with alarm.
- e) Emergency stop activated.
- f) Safety covering of washing machine open
- g) Malfunctioning of vapour exhaust system / Vapour exhaust blower overload

B. Interlock

- a) Washing machine stop - WATER STOP.
- b) Water injection start - when nozzle enters in the vials.
- c) Pressure of clean utilities - high & low

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

<b>one pharmaplan</b>	<b>User Requirement Specifications</b>				 <small>HLL BIOTECH LIMITED Chennai, India A Division of HLL Group</small>
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>	URS/VWD 01	
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>	02	

**6.2.2 Depyrogenation Tunnel**

A. Equipment should be capable to detect the following failure, notify the operator with alarm and shutdown the process:

- a) Emergency stop activated
- b) In feed empty
- c) In feed/ out feed jamming
- d) Motor overload
- e) Depyrogenation tunnel belt operation stops and resumes with difference in alarm.
- f) Maximum out feed reached in the in feed turntable of filling machine
- g) The differential air pressure in the depyrogenation zone must always be higher with respect to the drying zone and the cooling zone.

B. Interlock for depyrogenation tunnel

- a. Pressure differentials of pre-hot zone, sterilization zone, cooling zone out of set limit – machine should interlock
- b. Temperature of pre-hot zone, sterilization zone, cooling zone out of set limit – machine should interlock
- c. Fan of the heating zone stops working- Machine should interlock

**6.3 In –Process control**

6.3.1 Sampling valve for washing media (WFI) and compressed air to be provided at relevant location.

6.3.2 In case re-circulated water, suitable sampling provision is required.


**6.4 Level of Instrumentation**

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table:

Parameter	Purpose	Type of control and Instrumentation	Failure Mode Detection	Alarm
<b>Vial Washing Machine</b>				
Infeed/ Outfeed sensor	Vial counting	Sensor	NA	-
Sensor in the tunnel entry port	Over load tripping	Sensor	NA	Yes
Temperature	For monitoring, indicating the temperature of WFI supply	Temperature probe with transmitter, and indicator	Low or High	Yes

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

<b>nne pharmaplan</b>	<b>User Requirement Specifications</b>				 <small>HLL BIOTECH LIMITED                  100/101/102/103/104/105/106/107/108/109/110/111/112/113/114/115/116/117/118/119/120/121/122/123/124/125/126/127/128/129/130/131/132/133/134/135/136/137/138/139/140/141/142/143/144/145/146/147/148/149/150/151/152/153/154/155/156/157/158/159/160/161/162/163/164/165/166/167/168/169/170/171/172/173/174/175/176/177/178/179/180/181/182/183/184/185/186/187/188/189/190/191/192/193/194/195/196/197/198/199/200/201/202/203/204/205/206/207/208/209/210/211/212/213/214/215/216/217/218/219/220/221/222/223/224/225/226/227/228/229/230/231/232/233/234/235/236/237/238/239/240/241/242/243/244/245/246/247/248/249/250/251/252/253/254/255/256/257/258/259/260/261/262/263/264/265/266/267/268/269/270/271/272/273/274/275/276/277/278/279/280/281/282/283/284/285/286/287/288/289/290/291/292/293/294/295/296/297/298/299/300/301/302/303/304/305/306/307/308/309/310/311/312/313/314/315/316/317/318/319/320/321/322/323/324/325/326/327/328/329/330/331/332/333/334/335/336/337/338/339/340/341/342/343/344/345/346/347/348/349/350/351/352/353/354/355/356/357/358/359/360/361/362/363/364/365/366/367/368/369/370/371/372/373/374/375/376/377/378/379/380/381/382/383/384/385/386/387/388/389/390/391/392/393/394/395/396/397/398/399/400/401/402/403/404/405/406/407/408/409/410/411/412/413/414/415/416/417/418/419/420/421/422/423/424/425/426/427/428/429/430/431/432/433/434/435/436/437/438/439/440/441/442/443/444/445/446/447/448/449/450/451/452/453/454/455/456/457/458/459/460/461/462/463/464/465/466/467/468/469/470/471/472/473/474/475/476/477/478/479/480/481/482/483/484/485/486/487/488/489/490/491/492/493/494/495/496/497/498/499/500/501/502/503/504/505/506/507/508/509/510/511/512/513/514/515/516/517/518/519/520/521/522/523/524/525/526/527/528/529/530/531/532/533/534/535/536/537/538/539/540/541/542/543/544/545/546/547/548/549/550/551/552/553/554/555/556/557/558/559/560/561/562/563/564/565/566/567/568/569/570/571/572/573/574/575/576/577/578/579/580/581/582/583/584/585/586/587/588/589/590/591/592/593/594/595/596/597/598/599/600/601/602/603/604/605/606/607/608/609/610/611/612/613/614/615/616/617/618/619/620/621/622/623/624/625/626/627/628/629/630/631/632/633/634/635/636/637/638/639/640/641/642/643/644/645/646/647/648/649/650/651/652/653/654/655/656/657/658/659/660/661/662/663/664/665/666/667/668/669/670/671/672/673/674/675/676/677/678/679/680/681/682/683/684/685/686/687/688/689/690/691/692/693/694/695/696/697/698/699/700/701/702/703/704/705/706/707/708/709/710/711/712/713/714/715/716/717/718/719/720/721/722/723/724/725/726/727/728/729/730/731/732/733/734/735/736/737/738/739/740/741/742/743/744/745/746/747/748/749/750/751/752/753/754/755/756/757/758/759/760/761/762/763/764/765/766/767/768/769/770/771/772/773/774/775/776/777/778/779/780/781/782/783/784/785/786/787/788/789/790/791/792/793/794/795/796/797/798/799/800/801/802/803/804/805/806/807/808/809/810/811/812/813/814/815/816/817/818/819/820/821/822/823/824/825/826/827/828/829/830/831/832/833/834/835/836/837/838/839/840/841/842/843/844/845/846/847/848/849/850/851/852/853/854/855/856/857/858/859/860/861/862/863/864/865/866/867/868/869/870/871/872/873/874/875/876/877/878/879/880/881/882/883/884/885/886/887/888/889/890/891/892/893/894/895/896/897/898/899/900/901/902/903/904/905/906/907/908/909/910/911/912/913/914/915/916/917/918/919/920/921/922/923/924/925/926/927/928/929/930/931/932/933/934/935/936/937/938/939/940/941/942/943/944/945/946/947/948/949/950/951/952/953/954/955/956/957/958/959/960/961/962/963/964/965/966/967/968/969/970/971/972/973/974/975/976/977/978/979/980/981/982/983/984/985/986/987/988/989/990/991/992/993/994/995/996/997/998/999/1000</small>
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>	URS/VWD 01	
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>	02	

Level	For monitoring, indicating and controlling the level of WFI in re-circulating tank.	Level sensor, indicator with controller	Low or High	Yes
Pressure	For all clean utility inputs	Feedback for the machine to hold	Low or high	Yes
Speed	To adjust the vials speed	VFD	Low or High	Yes
<b>Depyrogenation Tunnel</b>				
Temperature	To monitor, control and record the temperature of drying zone	Temperature Transmitter	Low or High	Yes
Temperature	To monitor, control and record the temperature of depyrogenation zone (beginning)	Temperature Transmitter	Low or High	Yes
Temperature	To monitor, control and record the temperature of depyrogenation zone (end)	Temperature Transmitter	Low or High	Yes
Temperature	To monitor, control and record the temperature of cooling zone	Temperature Transmitter	Low or High	Yes
Air velocity	To measure air velocity of the tunnel laminar flow in all zones	Anemometer connected to PLC	-	Yes
Speed	To determine the conveyor speed	VFD	Low or High	Yes
Differential pressure	To monitor, control and record the differential pressure across HEPA filter	Pressure transducer	-	-
Differential pressure with respect to adjoining room	To monitor and record the pressure cascade from filling room to washing and sterilisation room between each zone.	Pressure transducer	-	-

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

HBL HLL BIOTECH LIMITED Manufacturing Division Chengalpattu, Chennai	User Requirement Specifications			
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel		
	Identification #:	-	Document No:	URS/VWD 01
	Effective Date	03-11-2014	Revision No:	02

Vial sensor	Vial overload in in-feed turntable of filling machine	Sensor	NA	Yes
-------------	---	--------	----	-----

**6.5 Batch data display and record printing**

Basic / standard data acquisition to be done in HMI. This should be mainly to collect the data by using external device.

Online printing using dot matrix printer along with strip chart recorder to be provided

**6.6 GMP requirements (Others)**

6.6.1 All parts of the machine exposed clean room area (Grade D/C/B) must be resistant to standard disinfectants or vendor should provide the name of specific disinfectants.

6.6.2 All Contact parts with the product and cleaning solution should be SS316L

6.6.3 The machine has to be designed in such way, that air turbulence is minimized.

6.6.4 All sensoric, controls, PLC, HMI, all LAF, Differential cascades, ventilators, exhaust fans should have provision to connect to the UPS supply.

6.6.5 Two power supply entry should be provided, the wiring of all mentioned above components should separate than the other components wiring i.e. one for UPS and another for main power supply.

6.6.6 Required support services, like cable tray/SS conduits/pendants outside the complete machine will be in client's scope.

6.6.7 Vendor should demonstrate 6 log reduction for viable germs and  $\geq 3$  log for endotoxins.

6.6.8 All product contact parts should be made with SS 316L

6.6.9 All non-product contact parts should be made with SS 304

6.6.10 All Gaskets should be made of food grade silicone /EPDM and should be non-toxic.

6.6.11 Equipment should be fitted with SS 316 L filter housing for all the utilities required.

**6.6.12 Vial washing**

a) Manual hood lifting system should be provided.

b) Machine should not have any hold up water in the machine. Slopes should be designed for complete draining of any hold-up water.

c) Machine should have manual intervention to start-up and end of cycle for flushing of hold water at intermediate washing steps if machine is stopped for sufficiently long interval.

d) The water collection tub should be completely drainable with drain valve for draining the water. The sloping inside the tub should be towards the drain point

e) When vial washing machine stops the machine should have suitable outputs to close the WFI user point valves to avoid dead lags.

f) After vial washing, vials should not be exposed to outer environment before entering to tunnel area.

g) Inching provision to be provided at both front end and back end side.


h) Manual override system to be provided for maintenance of the machine.

**6.6.13 Depyrogenation tunnel**



**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

<b>nne pharmanplan</b>	<b>User Requirement Specifications</b>				
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>	URS/VWD 01	
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>	02	


- a) All LAFs should have provision for UPS.
- b) The tunnel should be provided with a strip chart recorder for continuous monitoring of temperature of all zone, differential pressures between different zones & adjoining rooms and to record conveyor speed & power failure (if any). Recording time intervals should be adjustable on time to time basis.
- c) The connections of DEHS test in the side cladding of the tunnel have to be Tri-clover connections.
- d) The tunnel will have a night mode that will allow an energy-efficient mode of operation to hold temperature and sterility of the tunnel between batches.  
It has to be possible to reduce the temperature at night and at weekend with a programmable clock or manually. When temperature is below 100°C the fan of the heating zone is turned off.
- e) During IQ, Following validations (not limited to the points mentioned below) to be done by vendor
  - i. Demonstrate more than 3 log reduction of endotoxin.
  - ii. Heat distribution study- empty load
  - iii. Heat penetration study- with load
  - iv. Non viable particle count
  - v. Air velocity measurement
  - vi. Integrity of HEPA filters
- f) If temperature decreased below minimum set value, the conveyor should stop automatically.
- g) Validation document to give precise information on the time and minimum temperature exposure of vials inside the tunnel during depyrogenation at maximum vials output.
- h) Data Input requirements to be provided as mentioned below , but not limited to:
  - 1) Batch No
  - 2) Vial size
  - 3) Sterilization temperature (Minimum and Maximum values)
  - 4) Conveyor-off temperature
  - 5) Conveyor speed
- i) Vendor should provide suitable mechanism to ensure efficient depyrogenation during start-up of the cycle.

**6.7 Specific requirements**

- 6.7.1 Operating height: must be 900 mm ± 30 mm (to be finally decided during mock-up test of filling machine). The height of the machine has to be adjustable by means of adjustable legs.
- 6.7.2 Size of the opening of the tunnel (outfeed) at the filling room should be provided.
- 6.7.3 Physical separation between washing area and out feed area is required, to avoid glass splinters from spreading into open area.
- 6.7.4 In feed turntable should be designed to provide 3 minutes buffer to the machine speed.
- 6.7.5 All setting should be user adjustable and through the control panel whichever is possible.
- 6.7.6 All supply fans should be provided with variable frequency drives.

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

	User Requirement Specifications		
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel	
	<b>Identification #:</b>	-	<b>Document No:</b> URS/VWD 01
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b> 02

- 6.7.7 The complete machine and its components have to be designed and constructed to avoid stagnation of water (slope of at least 1%)
- 6.7.8 Cable between the single machines/units and the control cabinets inside the clean rooms are within the scope of delivery.
- 6.7.9 Control panel for the vial washing/tunnel should be in the vial washing/Tunnel room.
- 6.7.10 Vendor to provide the provision for removal of broken vials in vial washing machine.
- 6.7.11 This equipment should be compatible for integration with in-feed turntable of the filling and stoppering machine.
- 6.7.12 Vendor has to supply all the change-over parts, if any for all the different vials sizes as specified.
- 6.7.13 GMP toolbox should be provided as per requirement for changing the change-over parts and for general maintenance, which should include all the tools for the said machine maintenance.

**7.0 CONSTRAINTS**

**7.1 Equipment location and available space**

This equipment will be installed in the **Integrated Vaccines Complex, Chengalpattu.**

**Equipment Location:F1-VWD 01**

**Block:** Viral Vaccine Formulation

Floor: **Ground floor**

Room Dimensions (L x W): **5600mm x 6900mm**

Room No. **F1G042**

False ceiling height: **3000 mm**

The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1**. The equipment must be positioned as per the generic layout provided below.

**Physical condition of the rooms:**

Vial Washing and Sterilization Room:

1. Room will be non-hazardous
2. Class: EU Class "C"
3. Differential Pressure: 45 Pa Absolute
4. Temperature maintained: 22°C ±2°C
5. Relative Humidity: Not more than 55%

**Equipment Location:F1-VWD 02**

**Block:** Viral Vaccine Formulation

Floor: **Ground floor**

Room Dimensions: **5900mm x 7600mm**

Room No. **F1G085**

False ceiling height: **3000 mm**


The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1**. The equipment must be positioned as per the generic layout provided below.

**Physical condition of the rooms:**

Vial Washing and Sterilization Room:

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

<b>nne pharmanplan</b>	<b>User Requirement Specifications</b>				
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>	URS/VWD 01	
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>	02	

1. Room will be non-hazardous
2. Class: EU Class "C"
3. Differential Pressure: 45 Pa Absolute
4. Temperature maintained: 22°C ±2°C
5. Relative Humidity: Not more than 55%

**Equipment Location:F1-VWD 01**

**Block:** Bacterial Vaccine formulation

Floor: **Ground Floor**

Room dimensions (L x W): 6600mm x 6300mm

Room No:**F2G043**

False Ceiling height: **3000 mm**

The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1**. The equipment must be positioned as per the generic layout provided below.

**Physical condition of the rooms:**

Vial Washing and Sterilization Room:

1. Room will be non-hazardous
2. Class: EU Class "C"
3. Differential Pressure: 45 Pa Absolute
4. Temperature maintained: 22 °C ±2°C
5. Relative Humidity: NMT 55%

**7.2 Available Utility**

**Vial Washing & Depyrogenation machine**

- a) Electricity: Single (220 V) & 3 phase (420 - 440 V) (Report Requirement)
- b) Compressed air 6 bar, 21 CFM (Report Requirement)
- c) Purified water @ 3 to 3.5 bar, 900 LPH (Report Requirement)
- d) Chilled water @ 7 to 12 °C, 2 to 3 bar and 5 m<sup>3</sup>/hr (Report Requirement)
- e) WFI @ 3-5 bar at 80 deg C and 200 LPH (Report Requirement)

**Note:**

- Vendor to confirm on the above utilities provided for the equipment.
- Vendor to provide Pressure reducing valves and Pressure gauges along with the equipment as per equipment utility requirements.
- Vendor to provide all utility consumptions in details for the equipment during pre-bid.

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**


HBL HLL BIOTECH LIMITED Chennai, Tamil Nadu 600 026	<b>User Requirement Specifications</b>		
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel	
	<b>Identification #:</b>	-	<b>Document No:</b> URS/VWD 01
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b> 02

**8.0 ABBREVIATION**

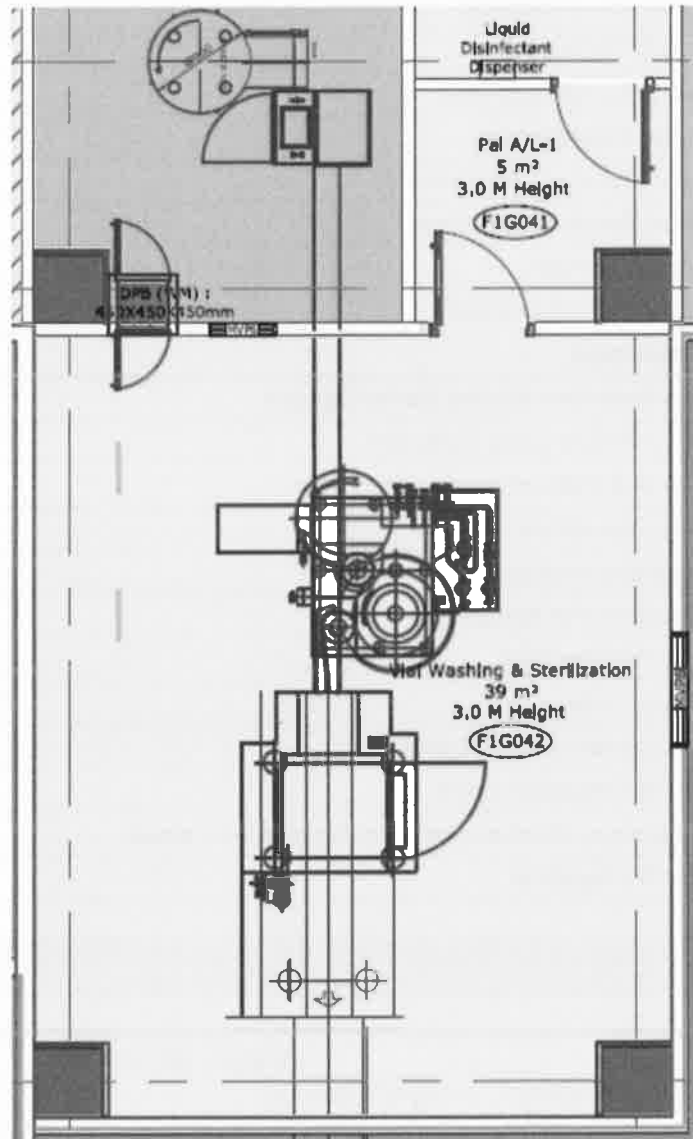
Abbreviation	Definition
CFM	Cubic Feet per Minute
DQ	Design Qualification
DEHS	Di-Ethyl-Hexyl-Sebacat
HBL	HLL BIOTECH LTD
FAT	Factory Acceptance Test
GA	General Arrangement
HEPA	High Efficiency Particulate Air
HMI	Human Machine Interphase
LPM	Liters Per Minute
MOC	Material Of Construction
NA	Not applicable
O-RABS	Open-Restricted Access Barrier System
PLC	Programmable Logic Controller
PID	Piping and Instrumentation Diagrams
QA	Quality Assurance
Ra	Roughness average
RPM	Revolutions Per Minute
RTP	Rapid Transfer Port
SS	Stainless steel
UPS	Uninterrupted Power Supply
VFD	Variable Frequency Drive
VWD	Vial Washing Machine with Depyrogenation Tunnel
WFI	Water For Injection


**9.0 REVISION INDEX**

Revision	Date	Reason for revision
00	29-09-2014	First Draft for Client's Review
01	20-10-2014	Updated as per comments received from HBL dated 17-10-2014 and 19-10-2014
02	29-10-2014	Updated as per HBL URS comment log sheet dtd 29-10-14

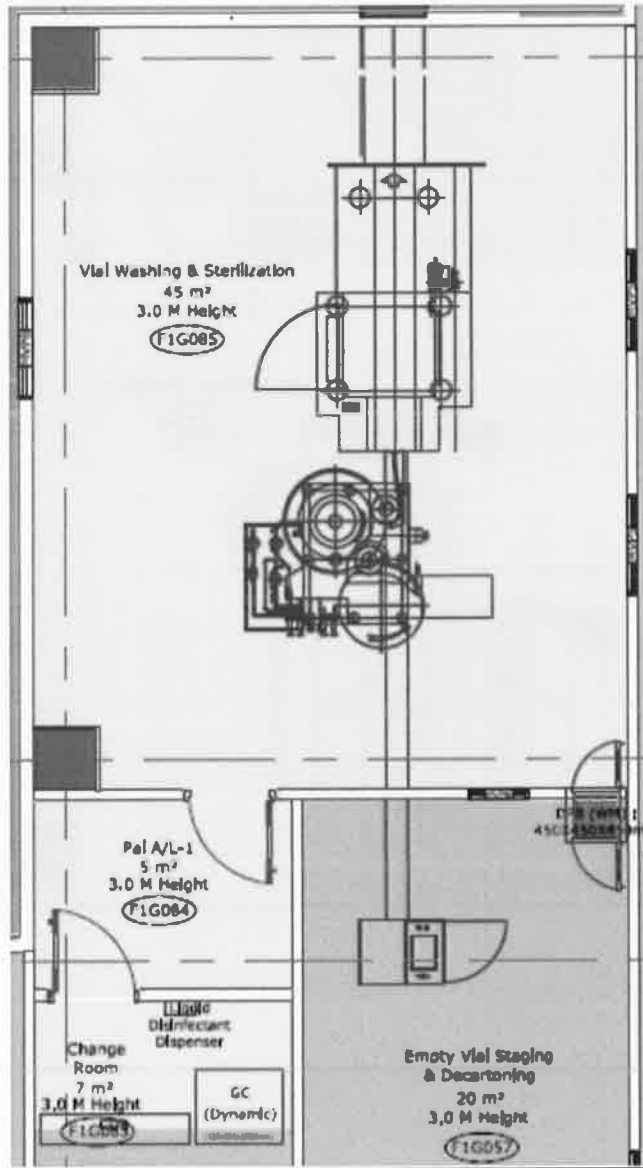
nne pharmaplan	<b>User Requirement Specifications</b>				
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VWD 01
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>		02

**URS Annexure 1: LAYOUT POSITION**  
**For F1-VWD 01**  
**Room Name: Vial Washing & sterilization**




nne pharmaplan	<b>User Requirement Specifications</b>				
	<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VWD 01
	<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>		02

**For F1-VWD 02**  
**Room Name: Vial Washing & sterilization**

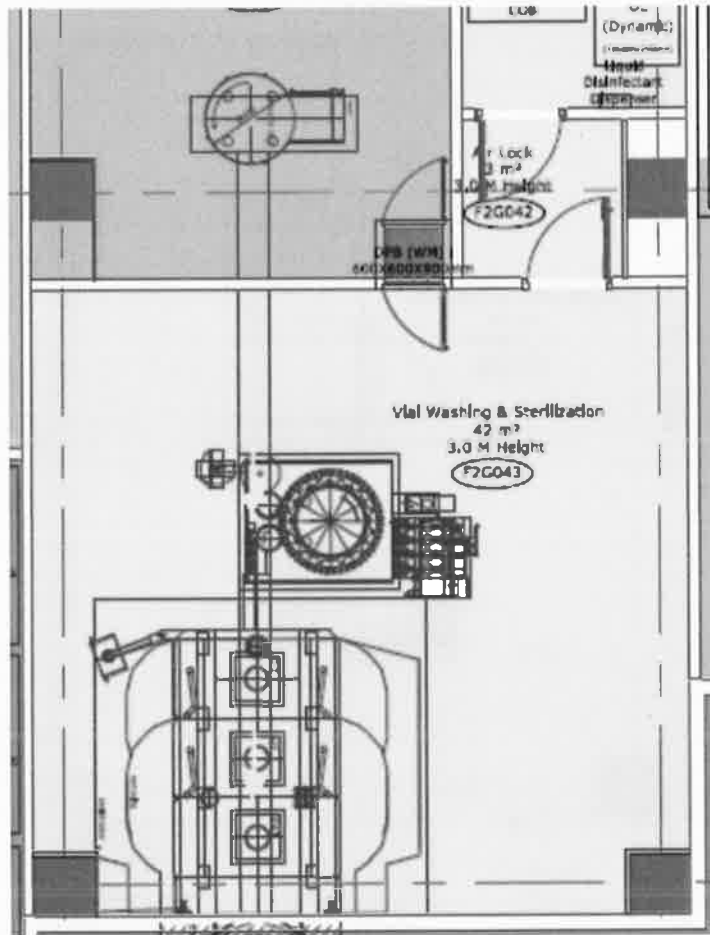


HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	User Requirement Specifications				
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel			
	Identification #:	-	Document No:		URS/VWD 01
	Effective Date	03-11-2014	Revision No:		02

**For F2-VWD 01**  
**Room Name: Vial Washing & sterilization**



**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

pharmaplan

**User Requirement Specifications**

<b>Equipment/System</b>	Vial Washing Machine with Depyrogenation Tunnel		
<b>Identification #:</b>	-	<b>Document No:</b>	URS/VWD 01
<b>Effective Date</b>	03-11-2014	<b>Revision No:</b>	02



**Annexure - 2**

**List of components and make for Vial Washing & Depyrogenation Tunnel**

S.No	Description	Preferred List
1.	Mobile guide position transmitter	Pepperl Fuchs / Novotechnik
2.	Pressure transmitter	Bourdon Haenni / Dwyer / Wika / Testo
3.	Main Drive Gear Motor	Bonfiglioli/Siemens
4.	Frequency Inverter	Allen-Bradley/ Siemens
5.	Gear Box	Bonfiglioli/Bauer
6.	Proximity Switch	Contrinex/Rockwell/Omron
7.	Proximity Sensor	Contrinex/Rockwell/Omron
8.	Pressure Transmitter	Rosemount / Dwyer / Wika
9.	Recirculatory Water Pump	Grundfos/Alfa Laval
10.	Peristaltic pump	Masterflex / Watson Marlow
11.	Pressure Gauge	Rosemount / Dwyer / Wika
12.	Solenoid Valve	Gemu / Burkert
13.	Filters & Filter Housing	Pall/Millipore/Sartorius
14.	Air Connection	Festo / SMC/Sweglok
15.	Temperature Sensors (PT-100)	E & H / Negele/Rosemount
16.	Pressure sensors	E & H / Negele/Rosemount
17.	PLC	Allen-Bradley/Honeywell/Siemens
18.	HMI	Allen-Bradley/Siemens
19.	Inlet shutter position sensor	Novotechnik / Pepperl Fuchs
20.	Transmitter for inlet gate position	Novotechnik / Pepperl Fuchs

**Annexure - 3**


**List of spares for Vial Washing & Depyrogenation Tunnel**

S.No	Description	Quantity per Equipment
<b>Vial Washing Machine</b>		
1.	Set of nozzles	1 Complete set
2.	Set of Grippers	1 Complete set
<b>Depyrogenation tunnel</b>		
3.	Overload Sensor	3 nos
4.	Heater bank / Heaters	1 Complete set
One complete set of heat resistant HEPA filters should also be provided.		



**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**


nne pharmaplan	<b>User Requirement Specifications</b>			 <small>HLL BIOTECH LIMITED                  Building: #101, Sector: 10, Phase: 1                  IT Enclave of IIT Madras</small>	
	Equipment/System	Vial Washing Machine with Depyrogenation Tunnel			
	Identification #:	-	Document No:		URS/VWD 01
	Effective Date	03-11-2014	Revision No:		02

**Annexure - 4**  
**Specifications of Customized vials**

15 ml glass vials (for use with 20 mm stoppers)		
S.No.	Tests	Specifications
1	Overflow capacity	15.50 ± 0.50 mL
2	Mouth internal diameter	12.60 ± 0.20 mm
3	Mouth external diameter	19.60 to 20.10 mm
4	Body outer diameter	24.0 ± 0.2 mm
5	Body wall thickness	1.00 ± 0.04 mm
6	Total height	49.7 ± 0.5 mm
7	Neck height	9.0 ± 0.5 mm
8	Collar height	3.9 ± 0.2 mm
9	Total weight	10.0 ± 1.0 g

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

<b>nne pharmaplan</b>	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	<b>Equipment/System</b>	Vial Sealing Machine			
	<b>Identification #:</b>	-	<b>Document No:</b>	URS/VSM 01	
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>	02	

## User Requirement Specifications Vial Sealing Machine

Block Code	Block Name	Identification #	Capacity	Qty [Nos]
F1	Viral vaccine formulation - Rabies	F1-VSM 01	200 Vials/Minute	1
F1	Viral Vaccine Formulation-Measles	F1-VSM 02	200 Vials/Minute	1
F2	Bacterial Vaccine Formulation	F2-VSM 01	200 Vials/Minute	1

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

nne pharmaplan

**USER REQUIREMENT SPECIFICATIONS**

Equipment/System	Vial Sealing Machine		
Identification #:	-	Document No:	URS/VSM 01
Effective Date:	03-11-2014	Revision No:	02




**URS Annexure List:**

URS Annex No.	Detail
1	Layout showing location of the installation of the Vial Sealing Machine
2	List of components and make
3	List of Critical spares
4	Specifications of customized vials

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**


nne pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	<b>Equipment/System</b>	Vial Sealing Machine			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VSM 01
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>		02

**Table of Contents**

<b>1.0</b>	<b>APPROVAL SIGNATURE.....</b>	<b>4</b>
<b>2.0</b>	<b>EQUIPMENT DESCRIPTION.....</b>	<b>5</b>
<b>3.0</b>	<b>PROCESS DESCRIPTION.....</b>	<b>7</b>
3.1	INPUT & CHARGING METHOD.....	7
3.2	BRIEF PROCESS STEPS.....	7
3.3	OUTPUT & DISCHARGING METHOD.....	7
<b>4.0</b>	<b>PRODUCTIVITY REQUIREMENT.....</b>	<b>7</b>
4.1	DESIRED/ SUGGESTED CAPACITY.....	7
4.2	STANDARD BATCH SIZE.....	8
4.3	CHANGE OVER TIME.....	8
4.4	OTHER PRODUCTIVITY REQUIREMENT.....	8
<b>5.0</b>	<b>CONTAINMENT.....</b>	<b>8</b>
<b>6.0</b>	<b>GMP REQUIREMENTS.....</b>	<b>8</b>
6.1	PROCESS CONTROL.....	8
6.2	FAILURE MODE DETECTION.....	8
6.3	IN-PROCESS CONTROL.....	9
6.4	LEVEL OF INSTRUMENTATION.....	9
6.5	BATCH DATA DISPLAY AND RECORD PRINTING.....	9
6.6	GMP REQUIREMENTS (OTHERS).....	9
6.7	SPECIFIC REQUIREMENTS.....	10
<b>7.0</b>	<b>CONSTRAINTS.....</b>	<b>11</b>
7.1	EQUIPMENT LOCATION AND AVAILABLE SPACE.....	11
7.2	UTILITY.....	13
<b>8.0</b>	<b>ABBREVIATION.....</b>	<b>13</b>
<b>9.0</b>	<b>REVISION INDEX.....</b>	<b>14</b>


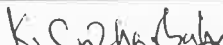
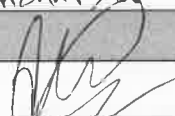
**HLL BIOTECH LIMITED, CHENNAI**

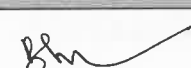
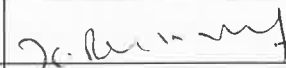

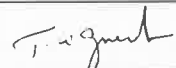


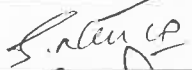
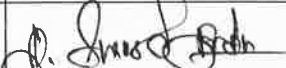
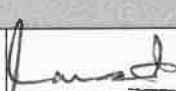
**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

NNE Pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	Equipment/System	Vial Sealing Machine			
	Identification #:	-	Document No:		URS/VSM 01
	Effective Date:	03-11-2014	Revision No:		02

**1.0 APPROVAL SIGNATURE**


This document is prepared by the Process, Validation and GMP Compliance team of "NNE Pharmaplan India" for the project "Integrated Vaccine Complex, Chengalpattu, Chennai" (**project number:** 120310) of HLL BIOTECH LIMITED (Chennai) under the authority of their Project Manager. Hence, this document before being effective shall be reviewed by the QA team of HBL, approved by Team lead and authorized by the appropriate Project authority.

NNE Pharmaplan India Limited			
Name	Designation	Signature	Date
<b>Prepared by</b>			
Mr. Yogesha M J	Process Engineer		29.10.2014
<b>Checked by</b>			
Mr. Sridhar Babu K	Senior Process Engineer		29.10.2014
<b>Approved by</b>			
Mr. Vikas Katial	GM & Head-COC Vaccines		29.10.2014

HLL Biotech Limited			
Name	Designation	Signature	Date
<b>Reviewed by</b>			
B. SATHESH	M Formulation (Viral/Vaccine)		30.10.2014
K. RADHAKRISHNAN	DM PRODUCTION		30.10.2014
G. RAMESH	DM (Bacterial Vaccine Formulation)		30.10.2014
VIGNESH KARAN	AM-PROJECTS		30.10.2014
<b>Approved By</b>			
Dr. Indira Devi Veerababu	Project Lead (V.V)		31/10/14
Dr. R. GOMARAN	DVP - Production		30.10.2014
G. NARASIMHA REDDY	Sr. Manager		30.10.2014
Dr. SURESH BABU	DM		31.10.2014
<b>Authorized by</b>			
RAMAN. K.R	CEO		03.11.2014

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

nne pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	<b>Equipment/System</b>	Vial Sealing Machine			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VSM 01
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>		02

**2.0 EQUIPMENT DESCRIPTION**

The vial sealing machine should consist of following parts in order to run operation smoothly.

S. No.	Description	Purpose
<b>1. Sealing Machine</b>		
1.	In feed Turn Table	To receive the full stoppered vials from Lyophiliser transferred through mobile LAF cart. (Only for F1-VSM-01 & F1-VSM-02)
2.	Vial receiving unit	To receive the full stoppered vials from Filling & stoppering machine transferred through turntable with mouse -hole. (Only for F2-VSM 01) <i>Note:- Filling &amp; Stoppering m/c cabinet to be flushed properly with vial Sealing m/c.</i>
3.	In feed star wheel, turret/screw	For uniform spacing
4.	Seal Hopper	Pre-sterilized seals should be loaded through O-RABS
5.	Chute	Used for feeding the flip-off seals to the sealing unit.
6.	Multi Head Sealing Unit	Sealing the vials of size specified under section <u>4.1</u>
7.	Out feed unit	a. The vials should be collected in a buffer tray (450 mm x 600mm) manually with a pushing device through a Dynamic Pass box in vial collection room (Vendor Scope). (for F1-VSM 01 and F1-VSM 02) b. To transfer the vials from the sealing unit and the vials should be transported through a half swing conveyor belt. The vials should be collected in a buffer tray (450 mm x 600mm) manually with a pushing device through a Dynamic Pass box in vial collection room (Vendor Scope). (for F2-VSM 01)

Machine should have all operation in automatic mode. All the regulatory requirements should be followed. The vial should be transferred to the sealing unit in a group by the transport system or by transport conveyor belt. (For lyophilized vaccines the vials should be unloaded from the Lyophiliser in frames and should be transferred onto the Mobile LAF Transfer Trolley. The same trolley should then be manually brought and docked to the feed turntable of the Vial Sealing Machine. The transfer of vials should be mechanized by means of pushing the frames transfer trolley onto the in-feed transfer table and lifting the frames manually).

The machine should be provided with the following interlocking.

1. The in-feed to turn table over load, the turntable should stop with alarm.
2. The infeed / out feed to sealing unit over load, the sealing machine should stop with alarm
3. No flip-off seal in chute, machine will stop with alarm.
4. If doors are open, the sealing machine should stop with alarm and recording
5. Vibrator overload, the sealing machine should stop with alarm

**All points of the IRS except the below mentioned would be applicable for the equipment**

- 4.1.11, 4.1.13, 4.1.17
- FDA Guidance for industry- Documentation for sterilization Process Validation
- ANSI/NSF 49-2008

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**


HBL HLL BIOTECH LIMITED Chennai	<b>USER REQUIREMENT SPECIFICATIONS</b>		
	<b>Equipment/System</b>	Vial Sealing Machine	
	<b>Identification #:</b>	-	<b>Document No:</b> URS/VSM 01
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b> 02

**Note:**

I.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
II.	The vendor is asked to state in "REMARKS" column with "yes" if the described requirement will be completely fulfilled and with "no" in case the requirement will not or cannot be fulfilled with the proposed equipment. In case of any deviation a comment must be inserted or enclosed as a separate annexure by referring to the respective URS specification number.
III.	The vendor must clearly comment each item of the Technical Specification. The comments must be in English language. If extra cost for necessary options becomes necessary the item must be clearly stated.
IV.	In case that the requirement includes a question or request or an information from the vendor, the answer / information should be stated in the "REMARKS" column.
V.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
VI.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
VII.	The vendor is responsible for technically unobjectionable function of the equipment. This TS is not intended to dictate a technical design to the vendor. If agreed upon with the vendor, the vendor can apply his practically proven design.
VIII.	Special Instruction a. If no comments against any specification should be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it should be treated as unresponsive / technically non compliant and rejected.
IX.	All the instruments and controls mentioned in the URS(s) are expected to be standard supply and part of your standard equipment model. In case of any deviation or redundancy or additional scope of supply is noticed, vendor is required to obtain clarification from HBL before submitting the quotes.
X.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
XI.	Refer document Installation Requirement Specification and Specific Instructions with URS; NPI-120310-IRS-S1-01
XII.	Refer Tender document with URS; NPI-120310-EQP-S1-TD-09

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

nne pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	<b>Equipment/System</b>	Vial Sealing Machine			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VSM 01
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>		02

Specifications		Remarks
----------------	--	---------

**3.0 PROCESS DESCRIPTION**

**3.1 Input & Charging method**

**3.1.1 Vial Sealing Machine**

**a) Full Stoppered Vials:**

- For F1-VSM 01 and F1-VSM 02:** The full stoppered vials in frames from the lyophiliser will be loaded on the trolley which will be transferred to the cassetting station of the vial sealing machine using mechanized transfer system and from cassetting station frames will be removed and transferred to the infeed turn table.
- For F2-VSM 01:** Full stoppered vials from the outfeed turntable with mouse-hole of the filling and stoppering machine are transferred to sealing unit through vial receiving unit.

**b) Sterilized flip-off Seals (according DIN ISO 8362-6):** External tyvek bag of seals should be removed and transferred using Flap type transfer port where second tyvek bag will be removed and charged within chute manually.

*Format : 13mm Nominal Size (for 2R and 4R), 20mm Nominal Size (for 6R), and 20mm Nominal Size (for customized vial)*

**3.2 Brief Process Steps**

**The vial sealing machine should follow the process as below**

- Transportation of stoppered vials either from stoppering station using transport conveyor or from Lyophilizer using Lyophilizer loading and unloading cart.
- Charging of the sterile flip-off seals to the chute of the vibrating hopper.
- Transportation of the seals from the hopper to the vials.
- Sealing of the vials by the sealing unit with the help of sealing rollers
- Interface: For F2-VSM 01:** Vendor to consider the provision to integrate the 2 potential free contacts in the sealing machine to communicate with the filling and stoppering machine. (Signal will be provided by filling and stoppering machine)

**3.3 Output & Discharging method**

- Transportation of the sealed vials by the conveyor through dynamic pass box and collection in the vial collection area. The vials should be collected in a buffer tray manually from the out feed of sealing unit by pushing device.
- Independent conveyor belt should be provided across the two hygiene zones with the dead plate in between to ensure smooth movement between vial sealing to vial collection station.

**4.0 PRODUCTIVITY REQUIREMENT**

**4.1 Desired/ suggested capacity**


The sealing machines should be suitable to produce specified line output for following size of vials;

F1-VSM 01	ISO 2R	As per DIN: ISO 8362-1 standard	200 Vials/min
	ISO 4R		200 Vials/min
F1-VSM 02	ISO 4R		200 Vials/min



**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

HLL Pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	<b>Equipment/System</b>	Vial Sealing Machine			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VSM 01
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>		02

F2-VSM 01	ISO 2R	200 Vials/min
	ISO 6R	200 Vials/min
	Customized vial	To be specified by vendor

*Refer the URS Annexure-4 for the specifications of the customized vials  
 Efficiency: Overall line efficiency of the Vial sealing machine is 100%*

**4.2 Standard batch size**

Standard batch size should vary ranging from 40,000 to 1,00,000 vials / batch.  
 Equipment should be able to run for 24 hours.

**4.3 Change Over Time**

Change part replacement should not take more than 30 minutes.

**4.4 Other Productivity Requirement**

- a) The vial sealing machine should have vial counter and reject vial counter.
- b) Any single change part should be not more than 5 kg.

**5.0 CONTAINMENT**

Not applicable

**6.0 GMP REQUIREMENTS**

**6.1 Process control**

**6.1.1 Sealing Machine**

- a) The equipment control system should be suitable to manually adjust and maintain the rate of sealing (number of vials/ minute).

**6.2 Failure mode detection**


**6.2.1 Sealing Machine**

**A. Equipment should be capable to detect the following failure, notify the operator with alarm and shutdown the process:**

- a) Emergency stop activated
- b) Alarm notification and process trip in case of infeed is empty
- c) Maximum infeed condition in turn table should notify the operator with alarm and stops the infeed from the stoppering station.
- d) Maximum out feed condition reached.
- e) Any toppled vial on transport conveyor.
- f) The vibrating bowl runs only on machine request. Hopper stops when machine is not working.
- g) Continuous detection of missing flip-off seals on sealing station.
- h) Alarm notification and process trips in case of reaching very low level of seals in hopper
- i) Rejection of vial, notify the operator with alarm.
- j) Cycle finish

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

HLL Pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	<b>Equipment/System</b>	Vial Sealing Machine			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VSM 01
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>		02

**B. Following Interlocks with alarm for procedural control**

- a) No Vial no seal
- b) No stopper no seal

**6.3 In –Process control**

Not applicable

**6.4 Level of instrumentation**

Sufficient and suitable instrumentation for the process, safety and productivity control as indicated in the following table, but not limited to the followings:

Parameter	Purpose	Type of control and instrumentation
Speed	To monitor and control the sealing speed with recording	Variable frequency drive
Quantity of vials	To count and indicate the number of vials at the in-feed	Digital counter
Quantity of vials	To count and indicate the number of reject vials	Digital counter
Hopper Vibration	To monitor, indicate and control the vibration speed.	Vibration indicator with controller.
Infeed/ outfeed sensor	To monitor the jamming or accumulation of the vials.	Optical sensor
Sensors	No bung no sealing	Optical sensor

**6.5 Batch data display and record printing**

Basic / standard data acquisition to be done in HMI. This should be mainly to collect and store the data using external device.  
Online printing using dot matrix printer to be provided

**6.6 GMP requirements (Others)**

**6.6.1 General**

- a) All vials with failures have to be rejected at the machine in a reject magazine.
- b) The internal vibration of the equipment should be considered in installation of the equipment.
- c) All process relevant wiring has to be executed in fail safe manner.
- d) Manual operation idling with tip switch must be possible for all applicable machines of the sealing line to be used during setup.
- e) All parts of the machine exposed in A/B area must be resistant to standard disinfectants or vendor should provide the name of specific disinfectants.
- f) All sensoric, controls, PLC, HMI and LAF should have provision for UPS connection.

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

**USER REQUIREMENT SPECIFICATIONS**

nne pharmaplan

**Equipment/System**

Vial Sealing Machine

**Identification #:**

-

**Document No:**

URS/VSM 01

**Effective Date:**

03-11-2014

**Revision No:**

02



g) Two power supply entry should be provided, the wiring of all mentioned above components should separate than the other components wiring i.e. one for UPS and one for main power supply.

h) Required support services, like cable tray /SS conduits /pendants outside the complete machine will be in client's scope.

**6.7 Specific requirements**

6.7.1 The Vial Sealing Machine should have open RABS with LAF for F1 VSM 01, F1 VSM 02 & F2 VSM 01  
Extended LAF to be provided on infeed turntable for docking the mobile cart [Only for F1 VSM 01 & F1 VSM 02]

6.7.2 The vial sealing machine should be provided with suitable vial receiving unit connecting the filling & stoppering machine with the sealing machine.[Only for F2 VSM01]

6.7.3 The complete cabling from the electrical cabinets to the single machines and to the further equipment is in the scope of delivery. Ladder rack cable supports will be provided within the building.

6.7.4 Operating height: must be 900mm ± 30 mm (to be finally decided during mock-up of sealing machine). The height of the machine has to be adjustable by means of adjustable legs and clearance from the bottom should be 200mm.

6.7.5 In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points e. g. pumps, motors, filters, etc.

6.7.6 As a special requirement the machine must allow set up by tip switches with cable.

6.7.7 The conveyor should be designed with minimum friction and have a possibility of height and width adjustment.

6.7.8 Vendor has to consider the monitoring of particles and microbiological sampling ports, monitoring system and necessary connection as per ISO 14644

6.7.9 The equipment control system should be suitable to adjust and maintain the rate of sealing (number of vials/ minute).

6.7.10 The design should ensure exchange of bulbs without cladding removal.

6.7.11 Appropriate loading and transport mechanism to be given for seals vibrating hopper in sealing machine.

6.7.12 Vendor has to provide all the change parts for all the different vials sizes as specified.

6.7.13 Machine setting should be automatic during changeover of all different vials

6.7.14 Tool box should be provided for general maintenance, which should include all the tools for the said machine maintenance.

**6.7.15 Turntable (only for F1-VSM 01 & F1-VSM02)**

a) Vendor to specify the diameter of the turntable.

b) Turntable should have own frame to dock the mobile LAF cart


c) Stability of vials to be considered for all mentioned vial sizes.

d) Integration of star-wheel to be considered.

e) Turntable should be integrated with ergonomic glove port.

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

nne pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	<b>Equipment/System</b>	Vial Sealing Machine			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VSM 01
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>		02

**6.7.16 Sealing Machine**

a) The equipment control system should be suitable to adjust and maintain the rate of sealing (number of vials/ minute).	
b) Vendor to specify the mechanism of loading of the sealing into the machine.	
c) Sealing pressure has to be adjustable and to be controlled.	
d) Specification of the sorting bowl/ hopper for stoppers should be provided.	
e) Vibrating hopper should be provided.	
f) Hopper guiding rail should be provided.	
g) Vendor to provide the diameter or the size of the chute to load the seals and number of seals which can be loaded in one go.	
h) Vendor to provide the diameter of the vibrating hopper and the finish of the bowl so that seals movement should be smooth.	
i) Pick and place system should be provided or vendor should provide better option.	
j) The conveyor belt should be designed with minimum friction and have a possibility of height and width adjustment.	
k) Inspection sensor should be provided at the sealing station to check for the no stoppered vials, not fully stoppered vials and the faulty vial will be rejected.	

**6.7.17 Reject Station**

a) Rejection station should be provided to collect faulty vials. (unsealed vials ).	
b) Vendor to specify proper rejection system should be provided to reject the rejected vials.	
c) Rejection station should have tray to collect the vials in front of the machine 90 degree to good vials collection.	
d) Optical sensor should be provided at the rejection tray to notify the operator if the tray is filled.	
e) Total count of the vial should be displayed and recorded	
f) Total no of reject vials should be displayed and recorded	

6.7.18 Comprehensive warrantee will commence after completion certificate and should be valid for 1 year

**7.0 CONSTRAINTS**

**7.1 Equipment location and available space**

This equipment will be installed in the **Integrated Vaccines Complex, Chengalpattu.**

**Equipment Location: F1-VSM 01**

**Block: Viral Vaccine Formulation-Rabies**

**Room No.: F1G043**


**Floor: Ground floor**

**Room Dimensions (L x W) : 10900mm x 6200mm, 5200mm x 7000mm**

**False ceiling height: 3000 mm**

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

<b>ne pharmaplan</b>	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	<b>Equipment/System</b>	Vial Sealing Machine			
	<b>Identification #:</b>	-	<b>Document No:</b>		URS/VSM 01
	<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>		02

The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1**. The equipment must be positioned as per the generic layout provided below.

**Physical condition of the rooms:**

Liquid Filling:

1. Room will be non-hazardous
2. Class: EU Class "B"
3. Differential Pressure: 65 Pa Absolute
4. Temperature maintained: 22°C ±2°C
5. Relative Humidity: Not more than 55%

**Equipment Location: F1-VSM 02**

**Block:** Viral Vaccine Formulation-Measles

Room No.: **F1G086**

Floor: **Ground floor**

Room Dimensions (L x W) : **10900mm x 6200mm, 4900mm x 4353mm**

False ceiling height: **3000 mm**

The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1**.

**Physical condition of the rooms:**

Liquid Filling:

1. Room will be non-hazardous
2. Class: EU Class "B"
3. Differential Pressure: 65 Pa Absolute
4. Temperature maintained: 22°C ±2°C
5. Relative Humidity: Not more than 55%

**Equipment Location: F2-VSM 01**

**Block:** Bacterial Vaccine Formulation

Room No.: **F2G044**

Floor: **Ground Floor**

Room dimensions (L x W): **12900mm x 5132mm, 6200mm x 2349mm**

False Ceiling height: **3000 mm**

The equipment location is indicated in the relevant block of the layout enclosed as **URS Annex-1**.


**Physical condition of the rooms:**

Filling room :

1. Room will be non-hazardous
2. Class: EU Class "B"
3. Differential Pressure: 65 Pa Absolute
4. Temperature maintained: 22°C ±2°C
5. Relative Humidity: <55% RH

# HLL BIOTECH LIMITED, CHENNAI

## INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	Equipment/System	Vial Sealing Machine			
	Identification #:	-	Document No:		URS/VSM 01
	Effective Date:	03-11-2014	Revision No:		02

### 7.2 Utility


- a) Electricity: Single (220 V) & 3 phase (420 - 440 V) (Report Requirement)
- b) Compressed air 6 bar (Report Requirement)
- Note: Vendor to provide Pressure reducing valves and Pressure gauges along with the equipment as per equipment utility requirements.**
- Vendor to provide the all utility consumptions in details for the equipment during pre-bid.

### 8.0 ABBREVIATION

Abbreviation	Definition
FAT	Factory Acceptance Test
GA	General Arrangement
GMP	Good Manufacturing Practice
HMI	Human Machine Interface
HBL	HLL Biotech Ltd
ISO	International Standards Organization
LAF	Laminar Air Flow
MOC	Material Of Construction
NPI	NNE Pharmaplan India LTD
O-RABS	Open- Restricted Access Barrier System
PID	Proportional Integral Derivative
PLC	Programmable Logic Controller
QA	Quality Assurance
Ra	Roughness Average
RTP	Rapid Transfer Port
SAT	Site Acceptance Test
SOP	Standard Operating Procedure
SS	Stainless steel
VSM	Vial Sealing Machine

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**


<b>nne pharmaplan</b>	<b>USER REQUIREMENT SPECIFICATIONS</b>			 <small>HLL BIOTECH LIMITED                  A Subsidiary of HLL Group Limited                  17, Narayanpet Road, Chennai</small>	
	Equipment/System	Vial Sealing Machine			
	Identification #:	-	Document No:		URS/VSM 01
	Effective Date:	03-11-2014	Revision No:		02

**9.0 REVISION INDEX**

Revision	Date	Reason for revision
00	19-07-2013	First Draft for Client's Review
01	20-10-2014	Updated as per comments received from HBL dated 17-10-2014 and 19-10-2014
02	29-10-2014	Updated as per HBL URS revision log sheet dated 28-10-2014

HLL BIOTECH LIMITED, CHENNAI

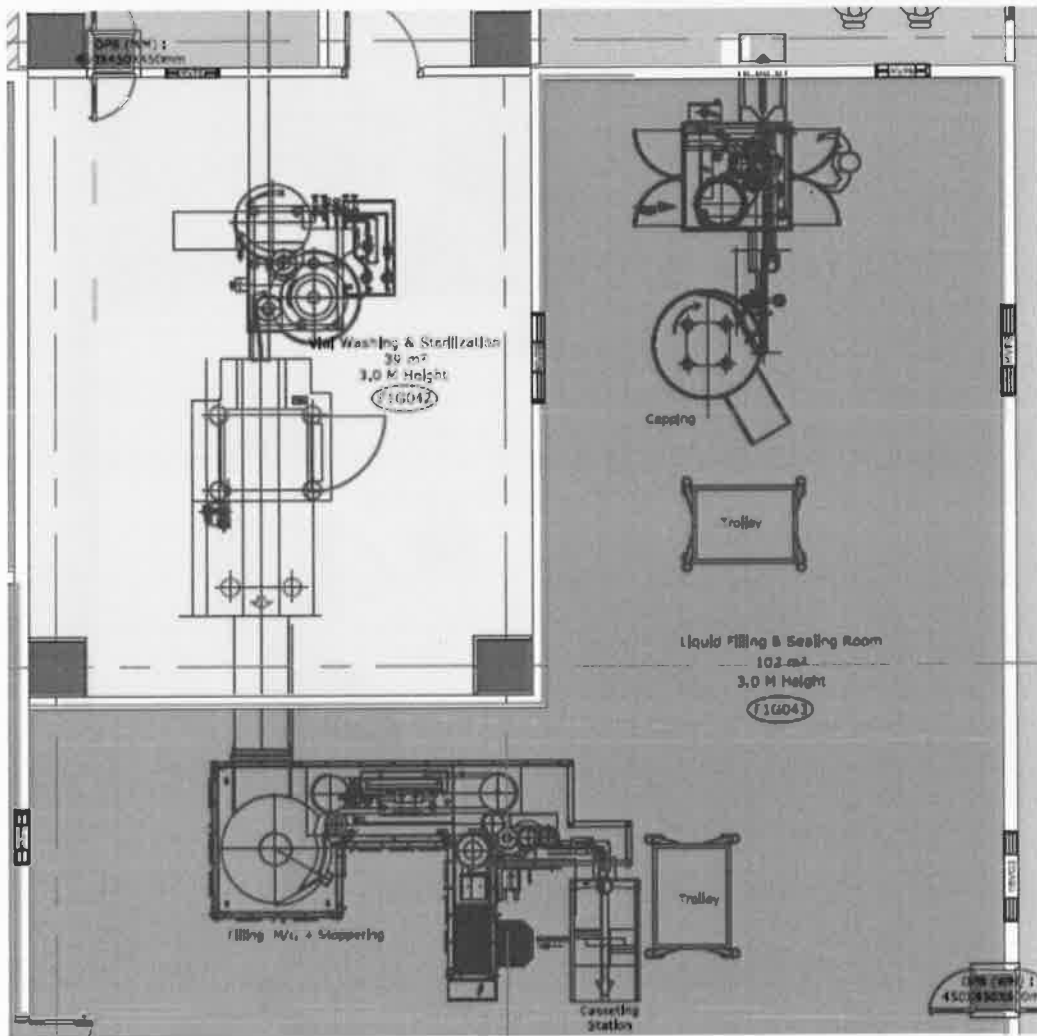
INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan	<b>USER REQUIREMENT SPECIFICATIONS</b>				
	Equipment/System	Vial Sealing Machine			
	Identification #:	-	Document No:		URS/VSM 01
	Effective Date:	03-11-2014	Revision No:		02

**URS Annexure 1: LAYOUT POSITION**

**For F1-VSM 01**

**Room Name: Liquid filling and sealing room**





HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

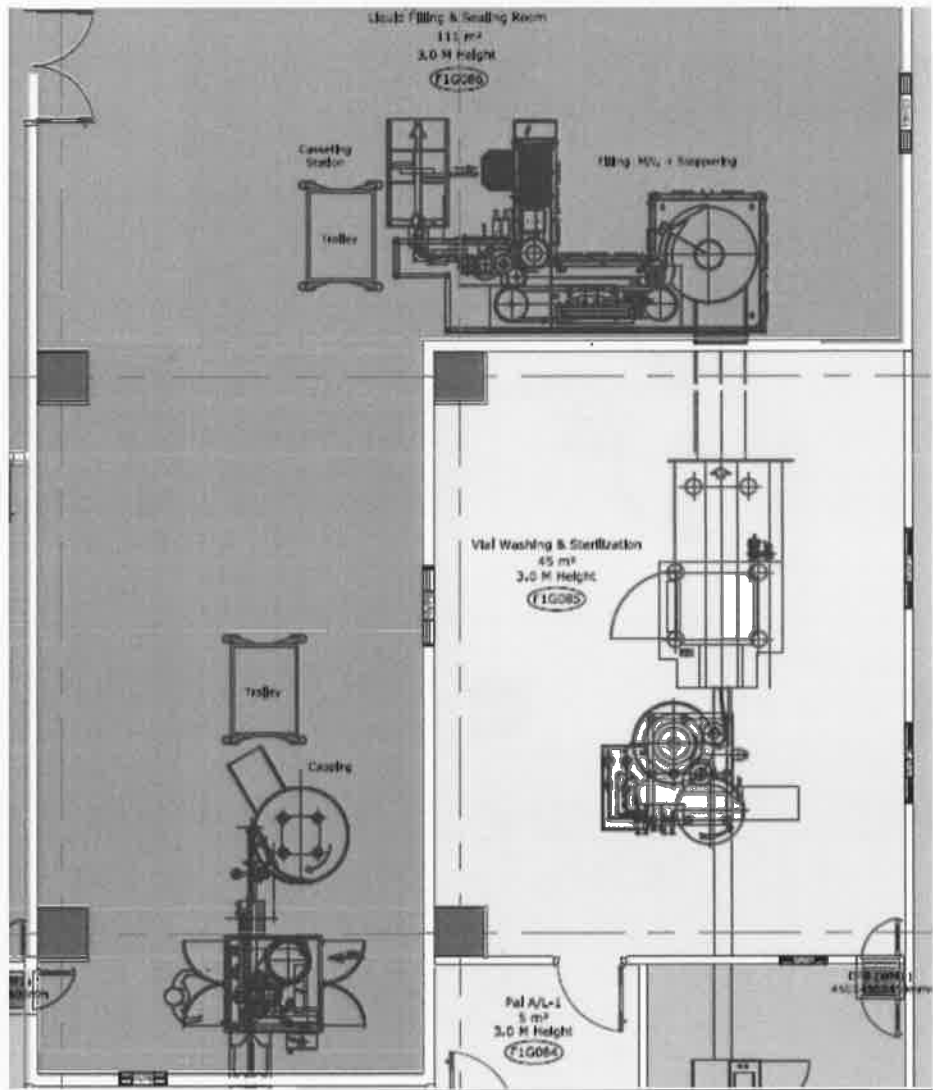
USER REQUIREMENT SPECIFICATIONS

Equipment/System	Vial Sealing Machine		
Identification #:	-	Document No:	URS/VSM 01
Effective Date:	03-11-2014	Revision No:	02




**For F1-VSM 02**

**Room Name: Liquid filling and sealing room**



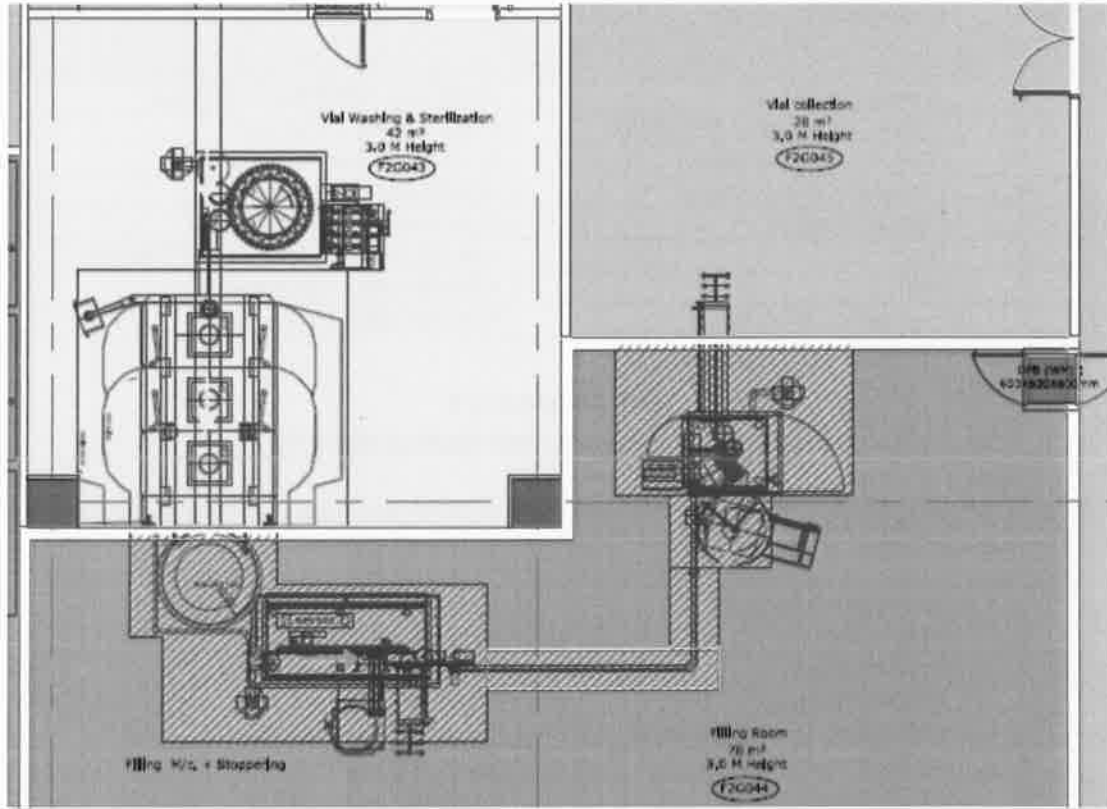
HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharma plan	USER REQUIREMENT SPECIFICATIONS				
	Equipment/System	Vial Sealing Machine			
	Identification #:	-	Document No:		URS/VSM 01
	Effective Date:	03-11-2014	Revision No:		02

**For F2-VSM 01**

**Room Name: Filling room**



**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

nne pharmaplan

**USER REQUIREMENT SPECIFICATIONS**

<b>Equipment/System</b>	Vial Sealing Machine		
<b>Identification #:</b>	-	<b>Document No:</b>	URS/VSM 01
<b>Effective Date:</b>	03-11-2014	<b>Revision No:</b>	02



**URS Annexure 2**

**List of components and make for Vial Sealing Machine**

S.No	Description	Preferred List
1.	Pressure Switch	Contrinex / Rockwell / Omron
2.	Electro pneumatic Regulator	Festo / Wika / Siemens
3.	Main Drive Gear Motor	Bonfiglioli / Siemens
4.	Conveyor Gear Motor	Bonfiglioli / Siemens
5.	Optical Sensor	Contrinex / Pepperl Fuchs
6.	PLC	Allen-Bradley / Honeywell / Siemens
7.	HMI	Allen-Bradley / Siemens
8.	Frequency Inverter	Allen-Bradley / Siemens



**URS Annexure 3**

**List of critical spares for Vial Sealing Machine**

S.No	Description	Preferred List per equipment
1.	Suspension Mounts	1 complete set (extra)
2.	Spring Set	1 complete set (extra)
3.	Vibrator Strip	1 complete set (extra)
4.	Sealer Profiler	1 complete set (extra)
5.	Motor with vibrating paddle	1 complete set (extra)
6.	All Mechanical Spares	1 complete set (extra)
7.	All Electrical spares	1 complete set (extra)

**HLL BIOTECH LIMITED, CHENNAI**

**INTEGRATED VACCINES COMPLEX, CHENGALPATTU**

	USER REQUIREMENT SPECIFICATIONS				
	Equipment/System	Vial Sealing Machine			
	Identification #:	-	Document No:	URS/VSM 01	
	Effective Date:	03-11-2014	Revision No:	02	

**Annexure - 4**  
**Specifications of Customized vials**

15 ml glass vials (for use with 20 mm stoppers)		
S.No.	Tests	Specifications
1	Overflow capacity	15.50 ± 0.50 mL
2	Mouth internal diameter	12.60 ± 0.20 mm
3	Mouth external diameter	19.60 to 20.10 mm
4	Body outer diameter	24.0 ± 0.2 mm
5	Body wall thickness	1.00 ± 0.04 mm
6	Total height	49.7 ± 0.5 mm
7	Neck height	9.0 ± 0.5 mm
8	Collar height	3.9 ± 0.2 mm
9	Total weight	10.0 ± 1.0 g

