User Requirement Specifications
Manual Optical Inspection Table

Block Code	Block	Identification #	Capacity L x W	Seating capacity	Qty Nos.
P1	Secondary Packaging Block	**P1-MOI-01**	(5000 x 1200) mm	20	1
P1	Secondary Packaging Block	**P1-MOI-02**	(5000 x 1200) mm	20	1

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URS Annexure List

URS Annex No.	Detail
1.	Layout showing location of the Optical Inspection Machine area

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 should 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.

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2.0 EQUIPMENT DESCRIPTION

The Manual Optical Inspection table for Vials is an Inspection system to Inspect Cracks, Cosmetic Defects and Unwanted Particles in Vials. The following in Vials defects which will be detected manually:-

Vials:-

- Particle Inspection.
- Glass
- Dark (Metal, Rubber etc.).
- Bright Fibres.
- Chips and Cracks.
- Colour of Solution or Cake.
- Cap and Crimp Inspection.
- Flip off Crack Defect in Inspection.

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

- 4.1.11
- 4.1.17
- ASME-BPE
- ANSI / NSF 49-2008, ISO 14664
- 5.4 - Material of constructions –Please refer the section: Specific requirement.
- 5.1 - Table 2, point 2,6 and 8

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 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-12

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
3.1.1. The operator will pick the tray with vials stored on pallet manually and keep it in the inspection area.	
3.2 Brief Process Steps	
3.2.1 Operator will pick the individual vial and inspect the vials against the white and black background under canopy lights should be considered.	
3.2.2 Good vials will be kept in separate tray.	
3.2.3 Operator will manually pick the defected vials and transport it to the rejection chute to collect it separately in rejection bin with lock and key arrangement.	
3.3 Output & Discharging method	
3.3.1 After inspection, the tray with good vials will be transported for next operations.	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	
The table should have 20 nos. of seating capacity with black and white canopy lights, magnifying glass to check filled vials.	
4.2 Standard batch size / process time	
Not Applicable	
4.3 Change Over Time (if applicable)	
Not Applicable	
4.4 Other Productivity Requirement	
Not Applicable	
6.1 Process Control	
6.1.1 There should be suitable rejection system contingent upon the product and the rejected product should be collected in separate tray or bin. This is applicable for all rejection stations.	
6.2 Level of instrumentation	
NA	
6.3 Batch data display and record	
NA	
6.4 GMP requirements (Others)	
NA	
6.5 Specific requirements	
6.5.1 The manual inspection table dimension should be approximately 5000 mm X 1200 mm.	

	Specifications	Remarks
	(L x W) **Note:** vendor to confirm the final dimension as per the design of the equipment.	
6.5.2	Manual inspection table should be with black and white canopy lights to check filled vials.	
6.5.3	20 No's of work station required for vial inspection.	
6.5.4	Partitions to be provided in the table for each operator/station.	
6.5.5	Station shall be two side seating type. (10 people in 1 row)	
6.5.6	The MOC of body shall be SS 304.	
6.5.7	The Optical inspection machine shall be easy to clean.	
6.5.8	Height of the table to be designed as per ergonomic requirements and it shall be adjustable type.	

7.0 CONSTRAINTS

7.1 Equipment location and available space

This equipment will be installed in the **Secondary Packaging Block** of **Integrated Vaccines Complex,** Chengalpattu.

i. **P1-MOI-01**

Equipment Location:

Room Name : **Secondary Packing Hall - 4**

Floor: **Ground floor**

Room No.:**P1G010**

Room Dimension : 29280x8015

False Ceiling Height : 3000 mm

ii. **P1-MOI-02**

Equipment Location:

Room Name : **Secondary Packing Hall - 1**

Floor: **Ground floor**

Room No.:**P1G011**

Room Dimension : 29280x7940

False Ceiling Height : 3000 mm

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

7.2 Available utility

NA

8.0 ABBREVIATION

Abbreviation	Definition

EU	European Union
FAT	Factory Acceptance Test
HBL	HLL Biotech Limited
I/O	Input / Output
IRS	Installation Requirement Specifications
GMP	Good Manufacturing Practice
ISO	International Standards Organization
MOC	Material of Construction
NA	Not Applicable
NPI	NNE Pharmaplan India
PRV	Pressure reducing valve
QA	Quality Assurance
OS	Operating System

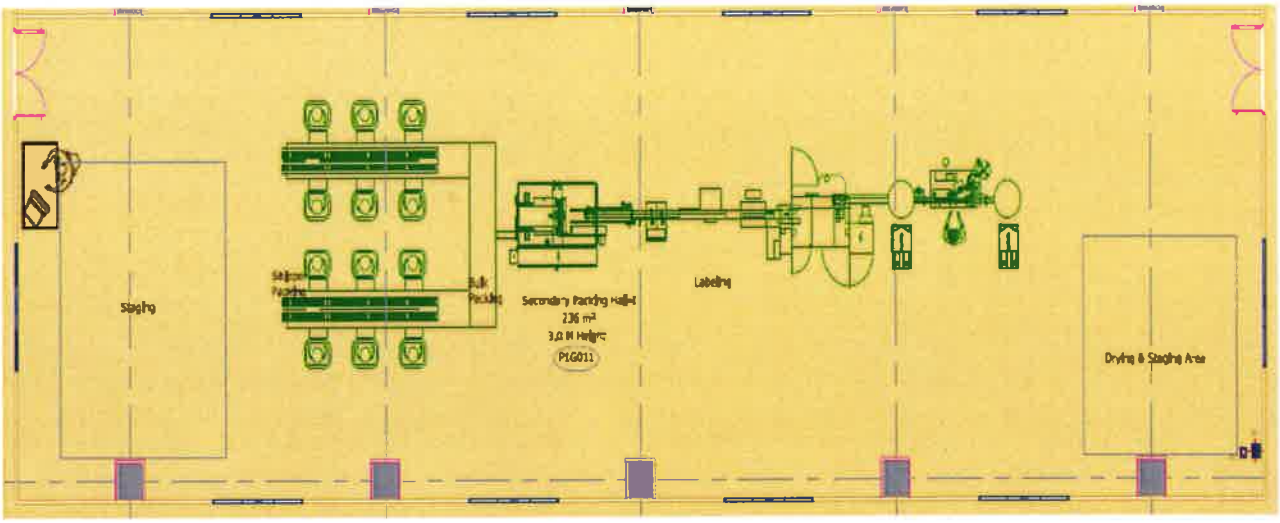
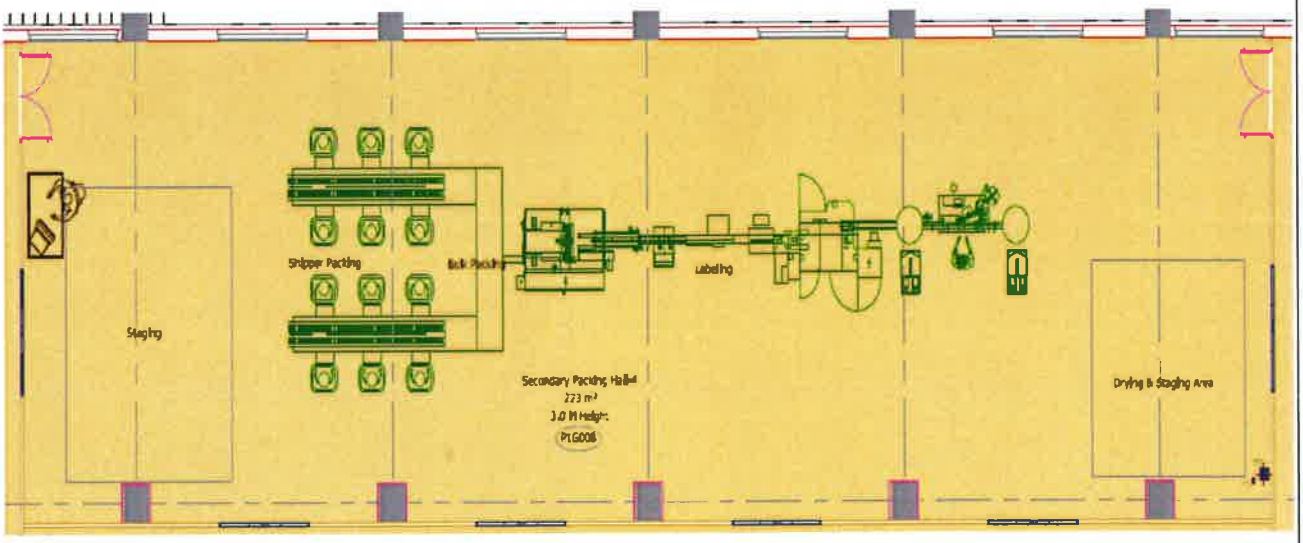
9.0 REVISION INDEX

Revision index

Revision	Date	Reason for revision
00	08-08-2014	First Draft
01	18-02-2015	Updated as per user inputs received by mail dated 18.02.2015
02	23-06-2015	Updated as per comments of HBL dated 19-06-2015
03	13-07-2015	Updated as per the telephonic discussion had with HBL on 13-07-2015

URS ANNEXURE 1: Layout showing location of the Secondary Packing Hall- 1 & 4

Room No: P1G011 – Manual Optical Inspection Table



Room No: P1G008 – Manual Optical Inspection Table