User Requirement Specifications
De-dusting Tunnel

Block Code	Block Name	Identification #	Capacity, (W x H x D), mm	Qty [Nos]
W1	Warehouse	W1-DTN-01	2300 X1450 X 2050 mm	1

URS Annexure List:

URS Annex No.	Detail
1	Layout showing location for the installation of the De-dusting Tunnel

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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**
Prepared by			
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Checked by			
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Approved by			
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HLL Biotech Limited			
Name	**Designation**	**Signature**	**Date**
Reviewed by			
User Department (Warehouse)	Dy. MANAGER PRODUCTION		
Project / Engineering Department	Dy. MANAGER (HVAC)		
Approved By			
Head of User Department (Warehouse)	DVP		
Head of Overall Department (QA)	DGM		
Authorized by			
Project Authority	CEO		

2.0 EQUIPMENT DESCRIPTION

De-dusting tunnels are used in pharmaceutical facility for capture/removal of the dust and dirt directly at the place of formation.

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
- ISO 14644
- ISO 8362
- 5.2.7, 5.2.8

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 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-14

Specifications	Remarks
3.0 PROCESS DESCRIPTION	
3.1 Input & Charging method	
Not Applicable	
3.2 Brief Process Steps	
Not Applicable	
3.3 Output & Discharging method	
Not Applicable	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Desired/ suggested capacity	

The capacities equipment is as follows

Sl. No.	Equipment ID	Capacity, (W x H x D), mm
1	W1-DTN 01	2300 X1450 X 2050 mm (Max Size of Box : 1000 x 1000 x1200 mm and Weight :1000 Kg)

4.2 Standard batch size	
Not Applicable	
4.3 Change Over Time	
Not Applicable	
4.4 Other Productivity Requirement	
Not Applicable	
5.0 CONTAINMENT	
Not applicable	
6.0 GMP REQUIREMENTS	
6.1 Process control	
Equipment should be controlled using control panel.	
6.2 In –Process control	
Not applicable	
6.3 Level of instrumentation	
Not Applicable	
6.4 Batch data display and record printing	
Not applicable	

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	Specifications		Remarks
6.5	**Technical Specification**		
6.5.1	Machine compliance	cGMP compliance	
6.5.2	Class of cleanliness	Class CNC	
6.5.3	Pre filters	20 microns	
6.5.4	Exhaust filters	G-4 (10 microns)	
6.5.5	Main supply filter	F-6 (5 micron)	
6.5.6	Roller conveyor with motor (in feed)	Shall be considered	
6.5.7	Roller dimension	W x D x H (vendor to confirm)	
6.5.8	Suction blower Motor	Shall be considered	
6.5.9	Exhaust Blower Motor	Shall be considered	
6.5.10	PBC (packing belt conveyor) Dimension (L x W)	Vendor to confirm	
6.5.11	Pressure gauges	Analog Pressure Gauge	
6.5.12	Quantity	1	
6.6	**Material of Construction**		
6.6.1	Outer Frame of the machine	SS 304, min 240 grit, Ra < 1.2 µm	
6.6.2	Chamber	MS painted/powder coated, Ra < 1.2 µm	
6.6.3	Roller Conveyor rolls	SS	
6.6.4	Conveyor assembly	MS painted/powder coated	
6.6.5	Motor fans	Aluminum Impellers, Ra < 1.2 µm	
6.6.6	All welds shall be ground finish		
6.7	**Specific Equipment requirement**		
6.7.1	Motor Blower shall be statically and dynamically balanced for less vibration and noise level. Mounting: spring suspension system to take care of vibration and noise.		
6.7.2	3 no. Magnehelic gauge shall be provided for pressure measurement (pressure drop) and for filters.		
6.7.3	On/ off switch for motor blower and light.		
6.7.4	Tunnel shall be provided with fluorescent lamp suitable to provide 400 lux level.		
6.7.5	Visual Notification system : a) audio alarm for motor b) clean down timer with indication c) Audio alarm system for pressure drop across the filter.		
6.7.6	Polyvinyl curtains shall be provided on the both sides to avoid doors and interlocking. Air curtains at material receipt side to be provided and interlocked with the start of conveyor		
6.7.7	Access Panel shall be in front and side wise for the maintenance.		
6.7.8	Machine will be surrounded with Grade "CNC" so vendor shall specify the intake and		

	Specifications	Remarks
	exhaust air flow rate	
6.7.9	Indicator Lamp/ LED light shall be provided on both the sides	
6.8	**Regulatory guidelines / standards**	
	Not applicable	
6.9	**Safety requirements**	
6.9.1	Emergency stop function on accessible area (both loading and unloading side)	
6.9.2	Noise level below 75 decibel at a distance of 1 m from the equipment.	
6.9.3	IP rating 54	
6.9.4	No sharp edges/Corners, crevices, pin holes in the process wetted parts of the equipment.	
6.9.5	In the event of equipment malfunction or loss of utilities, the unit must contain all necessary protection devices to ensure that the equipment and the product remain in a safe condition.	
6.9.6	Audio visual alarm system : a) Audio/visual alarm for Blower Motors & Conveyor Motors b) Clean down timer with indication. c) Audio alarm system for pressure drop across the filter.	
6.9.7	The heat given off by the unit must be stated.	
6.10	**Other requirement**	
6.10.1	Safe Zone shall be defined by the vendor to perform operations.	
6.10.2	Cleaning shall be done manually.	
6.10.3	Vendor to submit detailed fabrication drawing for approval before fabrication.	
6.10.4	Vendor to provide wall to wall coving for the equipment as well as floor to equipment coving at site	
6.10.5	SS Ramp shall be provided for loading & unloading side for easy material movement	
6.11	**Documents**	
6.11.1	DQ,IQ ,OQ,PQ as per approved format ,Material certificates, Steel	
6.11.2	Component Certificates like motor, proxy sensor, Fan, Filter etc.	
6.11.3	Operating instructions	
6.11.4	As built approved dimensional drawings and detail drawings	
6.11.5	Installation drawings and instructions	
6.11.6	As built approved electrical drawings	
6.11.7	Spare parts list	
6.11.8	Maintenance and service instructions	
6.11.9	Calibration certificates / protocols	

	Specifications	Remarks
6.11.10	Material certificates for non-metal parts (e.g. gaskets, O-rings, etc.)	
6.11.11	Documentation of installed hard- and software and configurations including Functional Design Spec. (FDS), Interlock Diagrams and Alarm List	
6.11.12	Noise level certificate	
6.11.13	Air Velocity Measurement and documents to be provided by the Vendor.	
6.11.14	Warranty certificate for 1 year from the date of installation.	

7.0 CONSTRAINTS

7.1 Equipment location and available space

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

Equipment Location: W1-DTN 01

Block: Warehouse

Room No.: **W1G001 & W1G102**

Floor: **Ground Floor**

Room Dimensions (L x W) : **Loading: 8700 mm x 4000 mm, unloading: 8700 mm x 4215 mm**

False ceiling height: **2400 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:

Receipt :

1. Class: Grade CNC
2. Differential Pressure: NA
3. Temperature maintained: Not more than 25 °C
4. Relative Humidity: Not more than 60%

7.2 Utility

a) Electricity: Single Phase (220 V) & 3 phase (420 - 440 V) (Report Requirement)

8.0 ABBREVIATION

Abbreviation	Definition
CNC	Controlled Not Classified
DQ	Design Qualification
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice

HBL	HLL Biotech Ltd
HMI	Human Machine Interface
IQ	Installation Qualification
ISO	International Standards Organization
MOC	Material Of Construction
NPI	NNE Pharmaplan India LTD
OQ	Operational Qualification
PQ	Performance Qualification
QA	Quality Assurance
RH	Relative Humidity
SS	Stainless steel
TBD	To be discussed
URS	User Requirement Specifications

9.0 REVISION INDEX

Revision	Date	Reason for revision
00	28-02-2015	First Draft for Client's Review
01	22-06-2015	Updated as per comments by HBL dated 09-06-2015

URS Annexure 1: LAYOUT POSITION
For Q1-FMH 01
Room Name: Receipt / Airlock