

Equipment Specification Data Sheet

Equipment Name: Vacuum Pump

Document No.: DS-VAP 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu


Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin QA & QC	Q1-VAP 01,02	-	2


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
Prepared by			
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Checked by			
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HLL Biotech Limited

Name	Designation	Signature	Date
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Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Vacuum Pump
	Project #	120310
	Document #	DS-VAP 01
		
1	Process requirements	
1.1	Vacuum pump is used for degassing and filtration of aqueous solutions.	
2	Equipment ID	
2.1	Q1- VAP 01,02	
3	Technical Specification	
3.1	Model	cGMP, Vendor to specify
3.2	Power supply	To be compatible to standard Indian Power Supply.
3.3	Noise Level	50 dB
3.4	Max Flow rate	Vendor to specify
3.5	Max Vacuum	min 61 cm (24 Hg)
3.6	Type	Diaphragm headed, Oil free Vacuum Pump
3.7	Motor Type	Permanent split capacitor
3.8	Free-air capacity	1 CFM (client to confirm)
3.90	Pump	Built in Motor mounted
3.10	Maximum Pressure	65 psig
3.11	Maximum Temperature	Vendor to specify
3.12	Dimension, (W X D X H)	Vendor to specify
3.13	Weight	Vendor to specify
3.14	Quantity	2 nos.
4	Material of Construction	
4.1	Body frame	cGLP Compliance
4.2	Wetted Parts	SS
5.3	Specific Equipment requirement	
5.4	Appropriate failure detection and alarm notification	
5.5	Chamber shall be insulated properly to maintain inner environment	
5.6	Proper earthing is necessary.	
5.7	Appropriate closure of all parts	
6	Other requirement	

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	Equipment Name	Vacuum Pump	
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6.1	Cleaning shall be done manually.		
6.2	All bolts, nuts on the exterior part of system will be with cap head or cap nut.		
6.3	Vendor to give code numbers for each component		
6.5	All parts of the system exposed in classified area must be resistant to standard disinfectants or vendor shall provide the name of specific disinfectants		
6.6	Vacuum Gauge		
6.7	Pressure Gauge		
6.8	Flexible Coupling		
6.9	Automatic drain valve		
7	Regulatory aspects		
7.1	cGLP compliances. Calibration certificate for pressure guage		
7.2	CE certification		
8	Safety requirements		
8.1	Always follow appropriate laboratory practices when using this equipment.		
8.2	Position and operate equipment in dry, clean and non combustible work surface.		
8.3	Do not allow the power cord to contact hot surfaces of the equipment accessories or sample.		
8.4	If spillage occurs, immediately disconnect the power supply to prevent fire hazard		
9	Documents		
9.1	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file		
9.2	IOQ Protocol.		
9.3	Warranty Letter for 1 year from the date of supply.		
9.4	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site		
9.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.		
9.6	All equipment warranty should be valid for one year from the date of completion.		
9.7	Vendor should provide list of standard spare parts with ordering information.		
9.8	Vendor should provide list of change parts (if applicable) with ordering information		
10	Timelines		
11.1	Not Applicable		
11	Preferred list of Makes		

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11.1	Thermofisher, Cole Parmer, PALL				
NOTE: Accurate size and technical specification need to be mentioned by the vendor					
TABLE NO: 1					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-VAP 01	Admin, QA & QC	Water test Lab	Q1S043	-	2400
Q1-VAP 02	Admin, QA & QC	Sterility test lab (Bacterial)	Q1S065	-	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
09-09-2015	Syed Sharique Ahmad	00	-	New document	
Table-3: Annexure					
Not applicable					

