

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

nne pharmaplan

REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR

Vacuum Tester

Project :

110831

Equipment ID :

See Annexure 1

Document :

DS-VAC 01



1 Process requirements

1.1 The vacuum tester shall be used to test the vacuum level present in the overhead space of the vials.

2 Technical Specification

2.1 Model Basic cGLP model, fully automatic

2.2 Test type Vendor to specify

2.3 Detected product Lyophilized Vials

2.4 Capacity 3 sec per test

2.5 Cycle time Should be adjustable according to test specification

2.6 Dimension(L x W x D) Vendor to specify

2.7 Maximum Spark Gap 30 mm

2.8 Expected operational hours per day 24 hrs

2.9 Performance requirement Must meet all applicable regulatory/pharmacopeial requirement of performance of equipment and its component to ensure accuracy and reproducibility in test results

2.10 Displaying, recording and printing of tests Required

2.11 Rapid change over time Less than 5 minutes

3 Utility

3.1 Electrical requirement Vendor to specify

3.2 Vacuum Vendor to specify

4 Material of Construction

4.1 Machine parts Vendor to specify

5 Specific requirement

5.1 The equipment should ensure the precise measurement of vacuum and moisture level in Vial.

5.2 The equipment must be portable and should be easy to clean

5.3 The noise level should be below 60 dB

5.4 The equipment must be simple to use

5.5 High sensitivity and high repeatability are desirable

5.6 Cycle time shall be adjustable according

5.7 Micro controller based control system

5.8 LCD display and RS232 shall be provided

6 Other requirements

6.1 The equipment must be portable

6.2 A training for chemists has to be included in the offer.

7 Regulatory guidelines / standards

7.1 Displaying, recording and printing of tests conducted

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR

Vacuum Tester

Project : 110831

Equipment ID : See Annexure 1

Document : DS-VAC 01



nne pharmanplan

8 Safety requirement

Following facilities must be provided to protect personnel and equipment:

8.1 Appropriate closure of all parts.

8.2 Proper earthing is necessary

9 Documentation

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

9.1 IOQ Protocol.

9.1 Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site

9.3 Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.

9.4 All equipment warranty should be valid for one year from the date of completion.

9.5 Vendor should provide list of standard spare parts with ordering information.

9.6 Vendor should provide list of change parts (if applicable) with ordering information

10 Timelines

Not Applicable

NOTE: Accurate size and technical specification need to be mentioned by the vendor.

AFI Approved for Enquiry

AFO Approved for Ordering

Mege

Pullest

01 01-09-2015

MGGP

PULM

☐☐

Rev Date


Completed By

Checked By

AFI

AFO

Sheet 1/2

DATA SHEET						
HLL BIOTECH LIMITED, CHENNAI						
nne pharmaplan	REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR				 HLL BIOTECH LIMITED <small>(Subsidiary of HLL Vaccines Limited) (A Company of India Enterprise)</small>	
	Vacuum Tester					
	Project #	110831				
	Equipment ID #					
	Document #	DS-VAC 01				
TABLE NO: 1						
Equipment ID	Block Name	Quantity	Room Name	Room No	Room dimension in mm	Room height in mm
B1-VAC 01	Diphtheria Block	1	Seed preparation	B1G047	3500 x 6510	3000
B1-VAC 02	Pertussis Block	1	Seed preparation	B1G008	3500 x 6510	3000
B2-VAC 01	Tetanus Block	1	Seed preparation	B2G028	4600 x 5280	3000
<div style="display: flex; justify-content: space-between;"> <div>AFI Approved for Enquiry</div> <div>AFO Approved for Ordering</div> </div>						
01	01-09-2015	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 2/2