

Equipment Specification Data Sheet

Equipment Name: Laser Particle Counter
Apparatus

Document No.: DS-LPT 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-LPT 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Tushar Shinde	Process Engineer	for <i>Tushar Shinde</i>	11-02-2016
Checked by			
Mr. Yogesha M J	Process Engineer	<i>Yogesha M J</i>	11-02-2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process	for <i>Harshad Mali</i>	11/02/2016

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
SANJEEV KUMAR R	Manager	<i>Sanjeev Kumar R</i>	15/02/2016
VIGNESHWARAN T	DM-PROCESS	<i>Vigneshwaran T</i>	15/2/16
Approved by			
V. SIVAKANESHI	Manager	<i>V. Sivakaneshi</i>	15/02/2016
Dr. SURESH BABU	DM - Q.C & QA	<i>Dr. Suresh Babu</i>	17.02.2016
Authorized by			
RAMAN K. R.	C.E.O	<i>Raman K. R.</i>	19.2.16

Equipment Specification Data Sheet

HLL Biotech Limited, Chennai

nne pharmaplan®

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

Equipment Name Laser Particle Counter Apparatus

Project # 120310

Document # DS-LPT 01



1 Process requirements

1.1 The Laser Particle counter apparatus shall be used to analyzing Parental and vaccine Diluents.

2 Equipment ID

2.1 Q1-LPT 01

3 Technical Specification

3.1	Particle Size Range	1.5 - 100 microns
3.2	No.of.Channels	8 or more
3.3	Flow Rate	10ml/min
3.4	Sensor Type	Vendor to specify
3.5	Sensor cell design	Vendor to specify
3.6	maximum concentration	Vendor to specify
3.7	Sample size	10 ml
3.8	Minimum sample size	> 10% of syringe volume
3.9	Sampling mode	Vacuum (Vendor to specify)
3.10	Light Source	Laser Diode
3.11	Wetted Surface material	Vendor to specify
3.12	Sample operating temperature	10- 40°C
3.13	Air Humidity	Vendor to specify
3.14	Communication	RS -232 interface or better
3.15	Calibration	Vendor to specify
3.16	Software	Particle contamination control s/w according to USP Pharmacopeia requirements and results according to USP, BP, EP, JP and facility to use individual in-house standards according to customer's definition. Display, printout and storage of analysis data as well as calibration check.

4 Material of Construction

4.1	Apparatus	Vendor to be specify
4.2	Equipment Connection	Vendor to be specify

5 Specific Equipment requirement

5.1	The equipment shall be compatible for cleaning with all standard disinfectants.
5.2	Training/demo for users on operations shall be provided.
5.3	The apparatus shall be closed container to avoid external contaminant.
5.4	Easy and convenient to operate
5.5	The apparatus shall be autoclavable


6 Other requirement


6.1	The equipment must be easy to clean and shall be compatible for cleaning with all standard disinfectants
6.2	Training for the users must be provided.

7 Regulatory aspects

7.1	Laser particle counter equipment should be meet USP, EU and Indian cGMP standards.
-----	--

8 Safety requirements

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Laser Particle Counter Apparatus
	Project #	120310
	Document #	DS-LPT 01
		
8.1	Appropriate closure of all parts.	
8.2	On power failure equipment should come in fail safe condition	
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	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site	
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
9.5	Warranty Letter for Minimum 1 year.	
9.6	Vendor should provide list of standard spare parts with ordering information.	
9.7	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	
11	Preferred List of Makes	
11.1	PMS, Light House, HAIC, Met-One, Markus Clotz	

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 HBL <small>HLL BIOTECH LIMITED (Subsidiary of HLL Lifecare Limited) (A Government of India Enterprise)</small>	
	Equipment Name	Laser Particle Counter Apparatus			
	Project #	120310			
	Document #	DS-LPT 01			
TABLE NO: 1					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-LPT 01	Admin, QA & QC				2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
09-10-2015	Krishna Amrutam	00	-	New document	
Table-3: Annexure					
Not applicable					

