User Requirement Specifications
Ultracentrifuge

Block Code	Area	Identification #	Quantity(Nos.)	Capacity
B1	Multiple Bacterial Bulk block – Hep B	B1-UCF 01-04	4	8 x [40+/-1] mL

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URS Annexure List

URS Annex No.	Detail
1	Layout showing location of the Ultracentrifuge in the Multiple Bacterial Bulk Block

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 shall 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 Equipment described in this URS is "Ultracentrifuge". The high speed Ultracentrifuge is used for separation of solid component from the liquid solution by using high centrifugal force.

SL. No.	Technical specifications	
1.	Capacity	8 Nos. x [40+/-1] mL
2.	Type of tubes used	Conical /Oak ridge/Quick seal polyallomer
3.	Rotor Type	Fixed Angle Rotor
4.	G Force required	5,00,000+/-10000 (xg)
5.	Speed, RPM	Vendor to specify
6.	Speed accuracy	± 2 RPM
7.	Speed setting range	Vendor to specify for settable range
8.	Timer	Required to set from 1 minute to 900 hours
9.	Cooling system	Required and shall CFC/HFC free
10.	Operating temperature	0 to 40 °C
11.	Temperature accuracy	± 0.5 °C
12.	Port for data transfer	USB or equivalent
13.	Batch data storage	Required for minimum 100 batches
14.	Acceleration and deceleration facility	Required with proper speed control for gradual increase/decrease
15.	Noise level	< 65 db

Note:

1.	This Technical Specification is the basis for an inquiry to a vendor and therefore the basis for the vendor's proposal.
2.	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.
3.	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.
4.	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.
5.	The final version of this document including the vendor's comments will become basis of a potential purchase order or contract.
6.	The Technical Specification serves to define a summary of all vendor's requirements concerning scope of delivery and services.
7.	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.
8.	Special Instruction a. If no comments against any specification shall be considered as "NO" and b. If there is no reply / comments against the complete URS by the vendor then it shall be treated as unresponsive / technically non-compliant and rejected.
9.	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.
10.	The makes requested are standard international makes. In case of any deviation, vendor to seek clarification from HBL before submitting the offers.
11.	Refer document "Installation Requirement Specifications and Specific Instructions" with URS NPI_120310_EQP_IRS_S1_01
12.	Refer tender document NPI_120310_EQP_S1_TD_17

All the points of the IRS except below mentioned points will be applicable for this URS

- 4.1.11, 4.1.13,
- ASME, ANSI / NSF 49-2008
- ISO 14644, ISO 8362
- 5.2.7, 5.2.8
- Heat exchanger, Insulation & cladding, Air break, CIP/SIP, Drain ability related points

HLL BIOTECH LIMITED, CHENNAI

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

User Requirement Specifications

Equipment/System	Ultracentrifuge		
Identification #	B1-UCF 01-04	Document No.	URS/UCF 01
Effective Date	18-04-2016	Revision#	01

Specifications	Remarks
3.0 PROCESS DESCRIPTION:	
3.1 Input & Charging method	
3.1.1 The tubes with product will be loaded on to the rotor manually and lid will be closed	
3.2 Brief Process Steps	
3.2.1 Process parameters will be fed in to the system through touch panel and process will be started	
3.2.2 The solid and liquid phases will be separated because of high centrifugal force	
3.3 Output & Discharging method	
3.3.1 The tubes shall be removed from the rotor manually for further processing	
4.0 PRODUCTIVITY REQUIREMENT	
4.1 Change Over Time	
Not Applicable	
4.2 Others(If any)	
Not Applicable	
5.0 CONTAINMENT	
Not Applicable	
6.0 GMP REQUIREMENTS	
6.1 Process control	
The equipment must operate and control the following process parameters.	
6.1.1 Control provision must be provided for Temperature , time , RPM	
6.2 Failure mode detection	
Equipment shall be capable to detect the following failure, notify the operator with alarm and shutdown the process: (if it exceeds by 0-10% (i.e. tolerance limit) of the set point value):	
6.2.1 Temperature deviation alarm	
6.2.2 Timer failure alarm	
6.2.3 Rotational speed Alarm	
6.2.4 Rotor Imbalance Alarm	
6.3 In – Process control	
6.3.1 Equipment shall be able to control the critical process parameters like RPM, temperature	

Specifications	Remarks
6.4 Level of instrumentation	
Not applicable	
6.5 Batch data display and record printing	
6.5.1 Batch data display should include these parameters i.e., set value and actual process value but not limited to these, • Time, Temperature, RPM, Operator Name	
6.5.2 Common software shall be provided to monitor all the equipment and it should be 21 CFR Part 11 Compliant	
6.5.3 Equipment should have provision to connect to the external printer with suitable interface for printing the batch data	
6.6 GMP requirements (Others)	
6.6.1 All product contact parts shall be cGMP compliant	
6.6.2 The system must be designed to fail in safe mode and to recover from safe mode without risk of contamination or product loss.	
6.7 Specific requirements	
In general the equipment has to be designed in a way to get easy and quick access to all necessary maintenance points.	
6.7.1 Vendor to provide the range of rotational speed of the Rotor in the Ultracentrifuge and shall be settable	
6.7.2 Audible and optical alarms to indicate the end of operation and to indicate other abnormality conditions	
6.7.3 Equipment shall be CE certified	
6.7.4 Cleaning shall be done manually. Vendor to provide the details about cleaning procedures and probable cleaning agents can be used	
6.7.5 Cooling mechanism should be provided to maintain the uniform temperature throughout the operation.	
6.7.6 Equipment shall be provided with over speed protection device.	
6.7.7 The rotor should be easily removable using minimum tools.	
6.7.8 Equipment shall be provided with automatic lid lock system	
6.7.9 Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure	
6.7.10 The system must be designed in such a way that, It should not start when lid is open	

Specifications	Remarks

7.0 CONSTRAINTS

7.1 Equipment location and available space

These equipment will be installed in the **Multiple bacterial bulk block** of **Integrated Vaccines Complex, at Chengalpattu**

B1-UCF 01-04:

Floor: Ground floor
Block Name: Multiple Bacterial Bulk Block
Section : Hepatitis-B
Room No. : B1G043
Room Area : 49 m^2
False ceiling height: 3000 mm

7.2 Available Utility

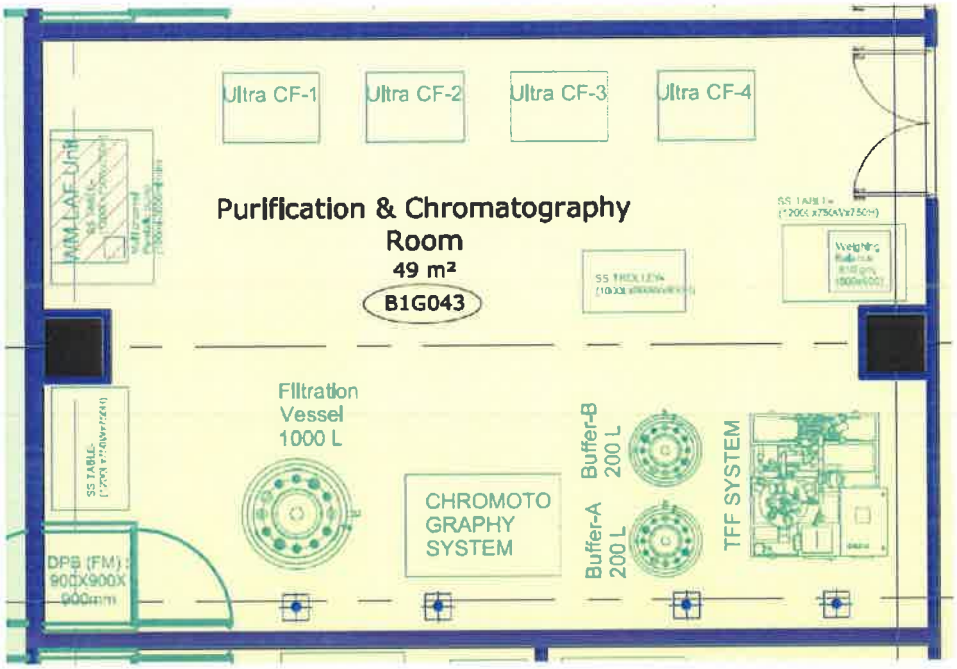
7.2.1 Electricity : (Report requirement) 230-240V, 50 Hz

8.0 ABBREVIATION

Abbreviation	Definition
cGMP	current Good Manufacturing Practices
GMP	Good Manufacturing Practices
HBL	HLL Biotech Limited
HMI	Human machine interface
IRS	Installation Requirement Specification
NA	Not Applicable
NPI	NNE Pharmaplan India Ltd
RCF	Relative Centrifugal Force
RPM	Rotations per minute
TBD	To be discussed
URS	User Requirement Specification

9.0 REVISION INDEX

Revision	Date	Reason for Revision
00	17-03-2016	New Document
01	05-04-2016	Updated as per the comments given by HBL dated 05-04-2016 in the hard copy

URS Annexure 1: LAYOUT OF MULTIPLE BACTERIAL BULK BLOCK

B1-UCF 01-04: Purification and Chromatography (B1G043), Hepatitis - B