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HBL HLL BIOTECH LIMITED

Equipment Specification Data Sheet

Equipment Name: Rapid Transfer port

Document No.: DS-RTP 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F1	Viral Vaccine Formulation	F1-RTP 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Ms. Niharika Ruhela	Process Engineer	For Sandeep	11-02-2016
Checked by			
Mr. Yogesha M J	Process Engineer	Yogesha-MJ.	11-02-2016
Approved 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		HBL HLL BIOTECH LIMITED
	Equipment Name	Rapid Transfer Port	
	Project #	120310	
	Document #	DS-RTP 01	

1	**Process requirements**	
1.1	The Rapid Transfer Port is used to perform aspetic liquid transfer between two areas with different containment classification.	
2	**Equipment ID**	
2.1	F1- RTP 01	
3	**Technical Specification**	
3.1	Quantity	1
3.2	Dimensions of External Port	Vendor to specify
3.3	Dimensions of Internal port	Vendor to specify
3.4	Tube Connection	Vendor to Specify
4	**Material of Construction**	
4.1	External Port Material	SS 316L
4.2	External Sealing Material	Silicone or Vendor to specify
4.3	Thickness requirement for wall	- Minimum wall thickness : Vendor to specify - Maximum wall thickness : Vendor to specify
4.4	Internal Port Material	SS 316L
4.5	Connector Body Material	Vendor to Specify
4.6	Overmolded Seal Material	Vendor to Specify
5	**Specific Equipment requirment**	
5.1	RTP system shall be compatible with either to transfer from SS vessel or as part of single use system (SUB).	
5.2	System shall be suitable for mulitiple transfer of different volumes without the need of re sterilization	
5.3	Mechanical interlocks shall be provided to prevent an accidental opening of the port and connector	
5.4	Connector device shall be 100% air leak proof	
5.5	Connector device shall be autoclavable.	
5.6	System shall ensure grade A continuity for aseptic processes.	

5.7	System shall complies cGMP requirements
6	**Other requirement**
6.1	NA
7	**Regulatory aspects**
7.1	ISPE Compliance
7.2	FDA Compliance
8	**Safety requirements**
8.1	All seals to be air tight tested.
8.2	Internal Port cannot be open without Connector Device in place
8.3	Their should not be any sharpe edges.
9	**Documents**
9.2	Material certificates for metal & non-metal parts (e.g. Stainless steel , gaskets,O-rings, etc.)
9.3	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site
9.5	Vendor should provide warranty letter for minimum 1 years, from the date of supply.
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**
10.1	Not Applicable
11	**Preferred list of Makes**
11.1	Sartorius
	NOTE: Accurate size and technical specification need to be mentioned by the vendor

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	Project #	120310			
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TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
F1-RTP 01	Viral Vaccine Formulation	Buffer preparation	F1G028	-	-

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
07-10-2015	Niharika Ruhela	00	-	New document

Table-3: Annexure

Not applicable