DATA SHEET

HLL LIFECARE LIMITED, TRIVANDRUM

nne pharmaplan®

Revival of BCG Vaccine Manufacturing Facility, BCGVL, Guindy, Chennai

BULK VESSEL

PROJECT #:	**110729**
EQ. ID #:	**FG-BLV 01**
DOCUMENT # :	**DS/FG-BLV 01**

1	**Process Steps**						
1.1	Bulk vessel shall be used in Bulk area as well for transferring of the final product to the filling area and the same shall be attached to the filling line. ***Refer Annexure 1***						
2	**Technical Specifications**						
2.1	Model	cGMP					
2.2	Type	Bulk product vessel (SS 316L) for filling machine					
2.3	Capacity	12 L Geometric volume (10 L working volume)					
2.4	Quantity	1 no.					
3	**Material Of Construction**						
3.1	Vessel	SS 316L					
3.2	Design	Cylindrical with flat bottom (Vessel Quality Certification- ASME BPE)					
3.3	Gaskets/ O-rings	PTFE / PVDF / VITON.					
3.4	Surface finish	Internally Electro polished Ra≤0.6 microns, conforming to SFC4, according to ASME BPE(2009).					
		Externally Mechanically polished up to ≤1.2 Ra					
		Flexible hosing shall be used (FDA approved material)					
3.5	Nozzles or ports	SS 316 L					
3.6	Nuts - bolts (internal, external, insulation support)	SS 316 L					
4	**Requirements**						
4.1	**Nozzles Schedule :**						
	Top Head Dish						
	• Top lid will be of TC connection with minimum of 4 inches diameter.						
	• 1no. Port for product inlet with S2S connection (TC clamps with gasket and Serrated nipple) for vent filter (Disc type).						
	• 1no. Port for vent filter with S2S connection (TC connection and serrated nipple) for bulk addition.						
	• 1no. spare port.						
	Bottom side wall						
	• Vessel should have side bottom discharge through manuval diaphragm valve and S2S connection for connection to buffer tank of filling line.						
4.2	• Fabrication of equipment and accessories should comply with the latest GMP standards.						
	• No sharp edges/Corners, crevices, pin holes should be there in the process wetted parts of the equipment.						
	• All welded joints, internal or external, shall be buffed and smooth for easy cleanability.						
	• Use of Asbestos is prohibited. Gasket material will be PTFE / PVDF / VITON.						
4.3	All nozzle pipes shall be seamless, unless otherwise specified.						
4.4	Flexible hosing/ tube shall be considered for transferring of the product, MOC: Silicone platinum cured						
4.5	Top lid shall be openable / flanged.						
4.6	Vessel to be designed to have minimum (< 0.5 %) dead volume.						
4.7	Vessel should have magnetic stirrer with magnetic bead (bar type). (*Vendor scope*)						
4.8	Vessel should have one number autoclaveable disc filter. *(Vendor scope)*						
4.9	The vessel shall be autoclaveable.						
4.10	Vendor to ensure 100 % drainability of the product.						
4.11	GA of the vessel and arrangement of the vessel shall be provided during the techno-commercial quotation.						
5	**Documents Required**						
5.1	DQ Document						
5.2	MOC certificates						
5.3	Test Certificate						
5.4	List of MAKE with certificate (to be used during fabrication of this unit)						
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.						
	AFI Approved for Enquiry AFO Approved for Ordering						
1	2013.05.02	BKSH	NVNG	☐	☐		
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/1	