DATA SHEET

HLL LIFECARE LIMITED, CHENNAI

nne pharmaplan®

REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR

BUFFER VESSEL

PROJECT #:	**110831**
EQ. ID #:	**F-BUV 01**
DOCUMENT # :	**DS/F-BUV 01**

1	**Process Requirement**			
1.1	Buffer vessel having formulated vaccine shall be used in filling area and the same shall be attached to the manifold of filling machine. (***Refer P&ID of Buffer vessel)***			
2	**Technical Specifications**			
2.1	Model	cGMP		
2.2	Type	Buffer vessel for filling machine		
2.3	Capacity	12 L Geometric volume (10 L working volume)		
2.4	Quantity	1 no.		
3.2	Design	Shell	Cylindrical	(Vessel Quality Certification- ASME BPE)
		Top dish	Flat type	
		Bottom dish	Torispherical type	
3	**Material Of Construction**			
3.1	Shell	SS 316L		
	Top dish	SS 316L		
	Bottom dish	SS 316L		
3.2	Gaskets/ O-rings	PTFE / PVDF / VITON.		
3.3	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) for connections between manifold of the filling line and buffer vessel.		
3.4	Nozzles or ports	SS 316 L		
3.5	Nuts - bolts (internal, external, insulation support)	SS 316 L		
4	**Specific Requirements**			
4.1	**Nozzles Schedule :**			
	Top Flat Head			
	• 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 bulk addition.			
	• 1no. Port for vent filter with TC connection.			
	• 1no. Port for product recirculation S2S connection (TC clamps with gasket and Serrated nipple)			
	• 1no. Port for level sensor.			
	• 1no. spare port.			
	Bottom Torispherical dish			
	• Vessel should have bottom discharge through actuated flush bottom valve and S2S connection for connecting the manifold of filling machine.			
4.2	• Fabrication of equipment and accessories should comply with the latest GMP standards.			
	• There should not be any sharp edges/Corners, crevices, pin holes 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.			
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 type.			
4.6	Vessel should have one number autoclaveable disc filter.			
4.7	The vessel shall be autoclaveable.			

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4.8	Vendor to ensure 100 % drainability of the product.
4.9	Vendor to provide the Valves V1, V2, V3 and V5 along with the peristaltic pump, which are indicated in the P&ID of this document.
4.10	GA drawing of the vessel and arrangement of the vessel should be provided by the vendor 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

Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1/1
0	2013.07.02	MJY	NVNG/VKKA	☐	☐	