

DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED Subsidiary of HLL Lifecare Limited (A Government of India Enterprise)</small>
	BUFFER VESSEL		
	PROJECT NO:	120310	
	EQUIPMENT ID:	F1-BUV 01	
	DOCUMENT NO:	DS/F1-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.		
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.	
2.5	Design	Shell	Cylindrical
		Top dish	Flat type
		Bottom dish	Torispherical type
(Vessel Quality Certification- ASME BPE)			
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 hoses 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 load cell.		
	• 1no. spare port.		
4.2	Bottom Torispherical dish		
	• Vessel should have bottom discharge through actuated flush bottom valve and S2S connection for connecting the manifold of filling machine.		
	• 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 hoses/ 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.		
4.8	Vendor to ensure 100 % drainability of the product.		
4.9	GA drawing of the vessel and arrangement of the vessel should be provided by the vendor during the techno-commercial quotation.		
5	Documents Required		

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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			
0	26.08.2013	MJY	SDBB	<input type="checkbox"/>	<input type="checkbox"/>
Rev	Date	Completed By	Checked By	AFI	AFO