

Equipment Specification Data Sheet

Equipment Name: Bursting Strength Apparatus

Document No.: DS/BSA 01

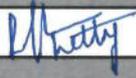
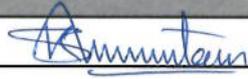
Revision: 00

Project No.: 120310

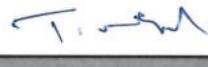
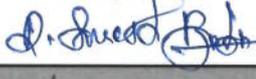
Project Name: Integrated Vaccines Complex, Chengalpattu

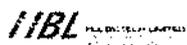
Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-BSA 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
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Mr. Krishna Amrutam	Manager - Formulation		2016-10-26

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
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Equipment Specification Data Sheet		
HLL Biotech Limited, CHENNAI		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Bursting Strength Apparatus
	Project No.	120310
	Document No.	DS/BSA-01
		
1	Process Requirement	
1.1	Bursting Strength apparatus is used for testing Packing materials like Shippers cartons and Bords etc	
2	Equipment ID	
2.1	Q1-BSA 01	
3	Technical Specification	
3.1	Model	cGLP
3.2	Range	0- 40.0 Kg/cm ²
3.3	Least Count	0.1 kg/cm ²
3.4	Pressure liquid	Hydrolic fluid (Glycerin or better)
3.5	Rate of Fluid Displacement	95 cc/min
3.6	Gear Box	Warm reduction Type
3.7	Fluid Tank Capacity	120 ml or better
3.8	Motor	1/4 HP Geared motor or better
3.9	Burst area	1 cm ²
3.10	Clamp	Manual
3.11	Power supply	To be compatible to standard Indian Power supply socket
3.12	Quantity	1 No
3.13	Dimensions (W x D x H) Internal Work area External dimensions	Vendor to specify
4	Material of Construction	
4.1	External body Construction	Cast Iron body for impacts
4.2	Internal body Construction	Cast Iron and fluid contact parts with SS
4.3	Clamp	SS with corrosion Resistant
4.4	Piston	Bras
4.5	Finshes	Design of the equipment should enhance cleaning by providing minimum sharp comers, minimum crevices and smooth finished welds joints
5	Specific Equipment Requirements	
5.1	Printer port along with compatable printer provided	
5.2	The body construction material have tempearture stability.	
5.3	The equipment shall be compatible for cleaning with all standard disinfectants	
6	Other Requirement	
6.1	Training/Demo for the users on operation and cleaning to be provided.	
7	Regulatory aspects	
7.1	CE certification	
8	Safety Requirements	
	Following facilities must be provided to protect personnel and equipment:	
8.1	Appropriate closure of all parts	
8.2	Proper earthing is necessary	
8.3	Noise level should be below 60 decible at a distance of 1m from the equipment	
9	Documents	
9.1	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editible electronic file	
9.2	IQQ document.	
9.3	Operation and maintenance manuals shall be provided along with IOQ & PQ documents during installation at site	
9.4	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
9.5	Warranty Letter for Minimum 1 year from the date of installation.	
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	

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10.1	Not Applicable				
11	Preferred list of Makes				
11.1	Presto, KD Labs				
	NOTE: Accurate size and technical specification need to be mentioned by the vendor				
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-BSA 01	Admin, QA & QC	Pkg. Mat. Lab	Q1S027	3915X2765	2400
Table-2: Change Log					
Date	Name / Initial	Revision	Section	Change/Comment	
16.10.2016	RHSE	00	-	New Document	