

Equipment Specification Data Sheet

Equipment Name: Rotary Bag Sealing Machine

Document No.: DS-BSM 01

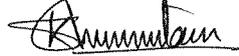
Revision: 01

Project No.: 120310

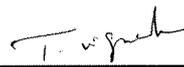
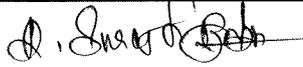
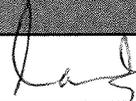
Project Name: Integrated Vaccines Complex, Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin QA & QC	Q1-BSM 01-02	-	2
F1	Viral Vaccine Formulation	F1-BSM 01-02	-	2
F2	Bacterial Formulation	F2-BSM 01-02	-	2
B4	Rabies Bulk	B4-BSM 01-02	-	2

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
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Checked by			
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HLL Biotech Limited

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HLL Biotech Limited, Chennai

nne pharmaplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HLL BIOTECH LIMITED <small>Subsidiary of HLL Lifecare Limited (A Government of India Enterprise)</small>
	Equipment Name	Rotary Bag Sealing Machine	
	PROJECT #:	120310	
	DOCUMENT # :	DS-BSM 01	

1 Process requirements

1.1 The bag sealing machine will be used to seal the tyvek / polypropylene bags.

2 Equipment ID

2.1	F1-BSM 01
2.2	F1-BSM 02
2.3	F2-BSM 01
2.4	F2-BSM 02
2.5	B4-BSM 01
2.6	B4-BSM 02
2.7	Q1-BSM 01
2.8	Q1-BSM 02

3 Technical Specification

3.1	Model	cGMP
3.2	Type	Automatic and Reproducible
3.3	Switch Off tolerance	± 5 °C
3.4	Quantity	8 Nos
3.5	Sealing seam width	12 and 15 mm (Approx)
3.6	Sealing Length	Unlimited
3.7	Process Parameters to be monitored	Sealing temperature, sealing speed and contact pressure
3.8	Pre-Heating Time required	Should be less than 4 minutes
3.9	Sealing Temperature	Max 220 °c (unit of temperature should be degree celcius)
3.10	Sealing speed range	10 m/min
3.11	Overall Dimensions (WxDxH)mm	550 mm (W) x 250 mm (D) x 150 mm (H)
3.12	Weight	Vendor to specify
3.13	Electrical Requirement	Power Consumption: Vendor to specify
3.14		220-230 V, 50 Hz , Single phase

4 Material Of Construction

4.1	Roll conveyor	SS 304
4.2	External Surface	SS 304
4.3	All welds shall be ground finish.	

5 Specific requirement

5.1	It should be possible to control sealing temperature, contact pressure and sealing speed and should be electronic type.
5.2	Energy saving function to be provided when the equipment is in stand-by mode
5.3	Equipment shall indicate, when thermostat has reached the preset temperature.
5.4	Equipment should have flexibility to accommodate different types of materials.(Tyvek and polypropylene bags etc.)

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5.5	Suitable heating source to be provided based on above mentioned materials and it should not over heat.		
5.6	In-feed guard to be provided.		
5.7	The set parameters should remain even after a power failure.		
5.8	Machine should stop with warning alarm in case the parameters exceed the predetermined limits.		
5.9	Roll conveyor to be provided along with this equipment.		
5.10	The sealing machine should work on microprocessor based controller.		
6	Other requirements		
6.1	Illuminated mains switch to be provided.		
6.2	Equipment should be easy to operate and easy to clean.		
6.3	Optimum sealing seam should be guaranteed when sealing temperature is correctly set		
6.4	On power failure equipment come to failsafe condition.		
6.5	Suitable enclosure to be provided for the equipment.		
6.6	Cleaning shall be done manually.		
6.7	Equipment should have provision for barcode printing and vendor to supply the barcode reader along with the equipment.		
7	Regulatory Aspects		
7.1	The Equipment should be able to efficiently sealing material according to EN 868-4, EN 868-5 and gusseted pouches		
7.2	The sealing machine should comply with DIN 58953-7		
8	Safety requirement		
8.1	Emergency stop function on accessible area.		
8.2	Automatic motor stop when the front lid or casing is opened.		
8.3	Appropriate closure of all the rotating parts.		
9	Documents		
9.1	IOQ documents		
9.2	MOC certificates		
9.3	Warranty for 1 year.		
9.4	Operation and maintenance manuals		
9.5	List of make with certificates.		
10	Timelines		
	NA		
11	Preferred list of makes		
11.1	Hawo		
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.		

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TABLE NO: 1

EQUIPMENT ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
F2-BSM 01-02	Bacterial Formulation	Preparation Room	F2G009	4900×9835	3000
F1-BSM 01	Viral Vaccine Formulation	Washing Area	F1G012	6250×6950	3000
F1-BSM 02	Viral Vaccine Formulation	Washing Area	F1G049	6250×6250	3000
B4-BSM 01	Rabies Bulk Block	Media Preparation	B4G027	6800×4150	2700
B4-BSM 02	Rabies Bulk Block	Wrapping for Sterilization	B4G030	6800×2550	2700
Q1-BSM 01	Admin QA & QC	Wash	Q1S050	6800 x 4300 1800 x 2700	2400
Q1-BSM 02	Admin QA & QC	Media preparation &sterilisation	Q1S052	5200×5649	2400

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
09-09-2015	Tushar Shinde	00	-	New document
26-10-2015	Tushar Shinde	01	All	Updated as per comments received

Table-3: Annexure

Not applicable

