

Equipment Specification Data Sheet

Equipment Name: Magnetic Stirrer with heating

Document No.: DS-MGH 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu


Block Code	Block Name	Identification No.	Capacity	Quantity
B4	Rabies Bulk	B4-MGH 01	-	1
B4	Rabies Bulk	B4-MGH 02	-	1
Q1	Admin QA & QC	Q1-MGH 01	-	1


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
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HLL Biotech Limited

Name	Designation	Signature	Date
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Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Magnetic Stirrer with heating
	Document No.	DS-MGH 02
	Revision No.	00
		
1	Process requirements	
1.1	The Magnetic stirrer will be used for uniform mixing and heating of product in glass bottle	
2	Equipment ID	Capacity
2.1	B4-MGH 01	To hold 1X20 L glass bottle/ unit of dia 300 mm
2.2	B4-MGH 02	To hold 1X20 L glass bottle/ unit of dia 300 mm
2.3	Q1-MGH 01	To hold 1X20 L glass bottle/ unit of dia 300 mm
3	Technical Specification	
3.1	Model	Table top cGMP, with media controlled heating
3.2	Dimension (W X D X H, mm)	Vendor to specify based on above mentioned capacities.
3.3	Features	Flat Surface LED display
3.4	Stirring volume, max	One unit of equipment to hold and operate with full capacity of 1 X 20 liter glass bottle.
3.5	Stirring speed	0-1000 RPM for 20 L
3.6	Temperature Range	Ambient to 200 °C with heat control accuracy of ± 5 °C
3.7	Display	LED Display
3.8	Power requirement	To be compatible to standard Indian Power Supply socket
4	Material of Construction	
4.1	Top plate	SS 304; Flat surface
4.2	Outer body	cGMP compliant
5	Specific Equipment requirement	
5.1	The external surface of the equipment should be easily disinfectable with standard disinfectants, and resistant to corrosion and chemicals. Stirrer should have smooth corners for easy cleaning	
5.2	Vibrations produced by the equipment during operation should be nil or minimum and should be specified by the vendor.	
5.3	Auto restart to set values upon power failures	
5.4	High magnetic adhesion preventing decoupling of stir bars	
6	Other requirement	
6.1	Standard accessories: 5 No.s PTFE coated magnetic stirring bars suitable to 100ml - 20L to be provided for each equipment.	
6.2	PTFE withdrawal system for magnetic stirring bars to be provided for each equipment	
6.3	Training/Demo for users on operation and cleaning to be provided.	
7	Regulatory aspects	
7.1	CE certification	

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8	Safety requirements	
	Following facilities must be provide to protect for personnel and equipment:	
8.1	Proper earthing should be provided.	
8.2	No sharp edges/ corners, crevices, pin holes in the equipment.	
8.3	Appropriate closure of all parts	
9	Documents	
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in the hard copy as well as editable electronic file	
9.1	IOQ documents	
9.2	Operations and maintenance manual shall be provided along with IOQ documents during installation at site	
9.3	Warranty letter for 1 year from the date of supply.	
9.4	Material test certificates	
9.5	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
9.6	List of standard spare parts with ordering information	
10	Timelines	
10.1	Not applicable	
11	Preferred list of Makes	
11.1	IKA, Mettler Toledo, Sartorius, Thermo scientific	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

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Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-MGH 01	Rabies Bulk	Media Preparation	B4G027	6800 X 3940	2700
B4-MGH 02	Rabies Bulk	Buffer Preparation	B4G028	6800 X 3845	2700
Q1-MGH 01	Admin QA & QC	Media Preparation	Q1S051	5200 X 3549	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
10/2/2016	Niharika Ruhela	00	-	New document	
Table-3: Annexure					
Not applicable					