

Equipment Specification Data Sheet

Equipment Name: Magnetic Stirrer

Document No.: DS-MGS 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
F2	Bacterial formulation	F2-MGS 01-02	-	2
F2	Bacterial formulation	F2-MGS 03	-	1
F2	Bacterial formulation	F2-MGS 04	-	1
B4	Rabies Bulk	B4-MGS 01-04	-	4
Q1	Admin, QA and QC	Q1-MGS 01	-	1
Q1	Admin, QA and QC	Q1-MGS 02-02	-	2

NNE Pharmaplan India Limited


Name	Designation	Signature	Date
Prepared by			
Ms. Niharika Ruhela	Process Engineer	<i>for Sandeep</i>	18/02/16
Checked by			
Mr. Yogesha M J	Process Engineer	<i>Yogesh M J</i>	18/02/2016
Approved by			
Dr. Harshad Mali	Lead Engineer - Process	<i>hml</i>	19/02/16

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
User department: Bacterial Formulation <i>S. Lakshmi</i>	Dy. Manager	<i>Chm</i>	04/03/16
User department: Rabies Bulk <i>P. NARAYAN KUMAR</i>	DY. MANAGER	<i>P. Narayan</i>	04/03/16.
User department: Quality Control <i>Sandeep Kumar - n</i>	Manager	<i>Sd</i>	29/02/16
Project Engineering department <i>A. ANTO FELIX</i>	Manager	<i>A. Antofelix</i>	29.02.16
Approved by			
Head of the department: Bacterial Formulation <i>S. NARAYAN KUMAR</i>	Gr. Manager	<i>S. Narayan</i>	04.03.2016
Head of the department: Rabies Bulk <i>Dr. J. Jeyasudhi</i>	Project head (w)	<i>J. Jeyasudhi</i>	04.03.2016.
Head of the department: Quality Control <i>V. Vignesh</i>	Manager	<i>V. Vignesh</i>	04.03.16
Head of the department: (QA) <i>A. Suresh Babu</i>	DyM	<i>A. Suresh Babu</i>	04.03.16
Authorized by			
Project Authority <i>P. Narayan K. R.</i>	C.E-O	<i>hml</i>	7.3.16

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Magnetic Stirrer
	Document No.	DS- MGS 02
	Revision No.	00
HBL HLL BIOTECH LIMITED A Division of HLL Group Limited A Division of HLL Group Limited		
1	Process requirements	
1.1	The Magnetic stirrer will be used for uniform mixing of product in glass bottle.	
2	Equipment ID	Capacity
2.1	F2-MGS 01-02	to hold 1X20 L glass bottle/ unit of dia 300 mm
2.2	F2-MGS 03	to hold 1X20 L glass bottle/ unit of dia 300 mm
2.3	F2-MGS 04	to hold 1X20 L glass bottle/ unit of dia 300 mm
2.4	B4-MGS 01-04	to hold 1X20 L glass bottle/ unit of dia 300 mm
2.5	Q1-MGS 01	to hold 1X20 L glass bottle / unit of dia 300 mm
2.6	Q1-MGS 02-02	to hold 1X20 L glass bottle / unit of dia 300 mm
3	Technical Specification	
3.1	Model	Table top cGMP, without heating
3.2	Dimension (W X D X H, mm)	Vendor to specify based on above mentioned capacities.
3.3	Features	Flat surface, for 20 L capacity 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	Operating Temperature	5°C - 37°C
3.7	Power requirement	To be compatible to standard Indian Power Supply socket
3.8	Number of stirring positions	one
3.9	Speed control	Vendor to specify
4	Material of Construction	
4.1	Top plate	SS 304; Flat surface
4.2	main body	cGMP compliant
5	Specific Equipment requirement	
5.1	The external surface of the equipment should be resistant to corrosion and chemicals. Stirrer should have smooth corners for easy cleaning.	
5.2	Vibration produced by the equipment during operation should be nil or minimum and should be specified by the vendor.	
5.3	High magnetic adhesion preventing decoupling of stir bars	
5.4	Auto restart to set values upon power failures	
6	Other requirement	
6.1	Standard accessories : 5 No.s PTFE coated magnetic stirring bars suitable to min 100 ml - 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.	

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
INTEGRATED VACCINES COMPLEX, CHENGALPATTU		
HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	Equipment Name	Magnetic Stirrer
	Document No.	DS- MGS 02
	Revision No.	00
7	Regulatory aspects	
7.1	CE certification	
8	Safety requirements	
	Following facilities must be provide to protect for personnel and equipment:	
8.1	Proper earthing should be provided.	
8.2	Appropriate closure of all parts.	
8.3	No sharp edges/ corners, crevices, pin holes in the equipment.	
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 shall be provided	
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, Shimadzu	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU				
	Equipment Name	Magnetic Stirrer			
	Document No.	DS- MGS 02			
	Revision No.	00			
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
F2-MGS 01-02	Bacterial formulation	Blending	F2G028	6090 X 8940	4000
F2-MGS 03	Bacterial formulation	Buffer & solution Preparation	F2G030	5127 X 6820	4000
F2-MGS 04	Bacterial formulation	Disinfectant Preparation	F2G024	2380 X 4910	4000
B4-MGS 01-04	Rabies Bulk	Virus Inactivation	B4G059	5750 X 3385	2700
Q1-MGS 01	Admin, QA and QC	Chemical Lab / Bio Chemistry	Q1S022	6260 X 7460	2400
Q1-MGS 02-02	Admin, QA and QC	Media preparation &sterilisation	Q1S051	5200 X 3550	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
10-02-2016	Ms. Niharika Ruhela	00	-	New document	
Table-3: Annexure					
Not applicable					