

Equipment Specification Data Sheet

Equipment Name: Magnetic Stirrer with heating

Document No.: DS-MGH 01

Revision: 03

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
Prepared by			
Ms. Niharika Ruhela	Engineer - Process		6/7/2015
Checked by			
Mr. Yogesha M J	Engineer - Process		6/7/2015
Approved by			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		6/7/2015

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
Navin Kumar P	Deputy Manager		9/7/2015
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Siva Ganesh V	Manager		10/7/2015
Suresh babu R	DGM		10/7/2015
Authorized by			
Raman. K. Ramachandran	CFO		13/7/2015

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED Subsidiary of HLL Lifesciences Limited (A Government of India Enterprise)</small>
	Equipment Name	Magnetic Stirrer with heating	
	Document No.	DS-MGH 01	
	Revision No.	03	
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 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 and timer required	
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 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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HLL Biotech Limited, Chennai		
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	Revision No.	03
		
8	Safety requirements	
	Following must be provided to protect the 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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HLL Biotech Limited, Chennai					
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 HBL HLL BIOTECH LIMITED <small>Subsidiary of HLL Lifescare Limited a Government of India Enterprise</small>	
	Equipment Name	Magnetic Stirrer with heating			
	Document No.	DS-MGH 01			
	Revision No.	03			
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	
11-07-2014	Nihanka Ruhela	00	-	New document	
09-09-2014	Niharika Ruhela	01	All	Updated as per comments received from HBL dated 04-08-2014	
08-01-2015	Yogesha M J	02	All	Updated as per comments given by HBL team during meeting dated 08-01-2015 at HBL office	
05-05-2015	Niharika Ruhela	03	All	Updated as per comments received from HBL dated 27-02-2015.	
Table-3: Annexure					
Not applicable					

Equipment Specification Data Sheet

Equipment Name: Magnetic Stirrer

Document No.: DS-MGS 01




Revision: 03

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, 02, 03, 04	-	4
Q1	Admin, QA and QC	Q1-MGS 01	-	1
Q1	Admin, QA and QC	Q1-MGS 02, 03	-	2

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Ms. Niharika Ruhela	Engineer - Process		6/7/2015
Checked by			
Mr. Yogesha M J	Engineer - Process		6/7/2015
Approved by			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		6/7/2015

Equipment Specification Data Sheet

Equipment Name: Magnetic Stirrer


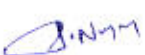







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Project Name: Integrated Vaccines Complex,
Chengalpattu

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
Lakshminarayanan	Deputy Manager		9/7/2015
Navin Kumar . P	Deputy Manager		8/7/2015
Sangeet Kumar . R	Manager		8/7/2015
Polina Sreenath	Deputy Manager		8/7/2015
Approved by			
Narasimha Reddy	Senior Manager		9/7/2015
Dr. Juliet Selvi	Head - viral Vaccine		10/7/2015
Siva Ganesh . V	Manager		10/7/2015
Suresh babu . R	DGM		10/7/2015
Authorized by			
Raman . R. Ramachandran	CEO		13/7/2015

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Magnetic Stirrer
	Document No.	DS- MGS 01
	Revision No.	03
		
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, 02, 03, 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, 03	to hold 1X5 L glass bottle / unit of dia 180 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 and timer required
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; 100-1500 RPM for 5 L
3.6	Operating Temperature	4°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 the capacities (5L and 20L) to be provided with 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.	

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7	Regulatory aspects	
7.1	CE certification	
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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	

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nne pharmaplan [®]	INTEGRATED VACCINES COMPLEX, CHENGALPATTU				<small>HLL BIOTECH LIMITED CHENGALPATTU CHENNAI</small>
	Equipment Name	Magnetic Stirrer			
	Document No.	DS- MGS 01			
	Revision No.	03			
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, 02, 03, 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, 03	Admin, QA and QC	Media preparation &sterilisation	Q1S051	5200 X 3550	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
11-07-2014	Niharika Ruhela	00	-	New document	
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