

Equipment Specification Data Sheet

Equipment Name: Vortex mixer

Document No.: DS-VOM 02

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
G1	Animal House	G1-VOM 01	-	1
G1	Animal House	G1-VOM 02	-	1
G1	Animal House	G1-VOM 03	-	1
G1	Animal House	G1-VOM 04	-	1
G1	Animal House	G1-VOM 05	-	1
Q1	Admin, QA and QC	Q1-VOM 01	-	1
Q1	Admin, QA and QC	Q1-VOM 02-03	-	3
Q1	Admin, QA and QC	Q1-VOM 05	-	1
Q1	Admin, QA and QC	Q1-VOM 06	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
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Checked by			
Mr. Yogesha M J	Process Engineer	<i>Yogesha-MJ</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			
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Process / Engineering department <i>A. Anil Felix</i>	Manager	<i>A. Anil Felix</i>	29.02.16
Approved by			
Head of the department Animal House <i>D. K. A. Dev Kumar</i>	Manager	<i>D. K. A. Dev Kumar</i>	03.03.16
Head of the department Quality Control <i>S. V. Srinivasan</i>	Manager	<i>S. V. Srinivasan</i>	04/03/16
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Project Authority <i>R. R.</i>	C.E.O	<i>R. R.</i>	7-3-16

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
HLL Biotech Limited INTEGRATED VACCINES COMPLEX, CHENGALPATTU	Equipment Name	
	Vortex Mixer	
	Document No.	
	DS-VOM 02	
Revision No.		00
		
1	Process requirements	
1.1	Used to mix liquids to make homegenous suspensions.	
2	Equipment ID	
2.1	G1-VOM 01	
2.2	G1-VOM 02	
2.3	G1-VOM 03	
2.4	G1-VOM 04	
2.5	G1-VOM 05	
2.6	Q1-VOM 01	
2.7	Q1-VOM 02-03	
2.8	Q1-VOM 05	
2.9	Q1-VOM 06	
3	Technical Specification	
3.1	Model	cGMP compliant
3.2	Type	table top
3.3	Speed range	100 to 3200 rpm
3.4	Operating temperature	4 °C to 65 °C
3.5	Operating modes	yes
3.6	Touch mode	yes
3.7	Continuous mode	yes
3.8	External Dimension (W x H x D) mm,	vendor to specify
3.9	Type of movement	Shaking / vortexing
3.10	Power Requirement	To be compatible to standard Indian Power supply
3.11	Permissible shaking weight	vendor to specify
3.12	Quantity	11 Nos.
3.13	Speed	Variable speed control allows slow speed shaking action up to high speed vortexing
4	Material of Construction	
4.1	Main body	Nitrile rubber
4.2	Head	Polyethylene

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nne pharmaplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Vortex Mixer
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5	Specific Equipment requirement	
5.1	Equipment shall be compatible for cleaning with all standard disinfectants.	
6	Other requirement	
6.1	Automatic press start, continuous run or touch activated run modes.	
6.2	Easy switch with optional heads to hold variety of test tubes. Rubber single cup tube holder and foam pad for mixing flasks or multiple tubes simultaneously.	
6.3	Equipment should have cold room / incubators compatibility and spill proof electronic use.	
6.4	Should be stable at high speeds	
6.5	Heavy duty cast metal base with rubber feet assures stability and eliminates creep during operation.	
6.6	Training / Demo for the users on operation and cleaning shall be considered	
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	On power failure equipment should come in fail safe condition	
9	Documents	
	Following documents, but not limited to these, are expected from the vendor as part of the supply package in hard copy as well as editable electronic file:	
9.1	IOQ Document	
9.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site	
9.3	Warranty letter for 1 year from the date of supply.	
9.4	List of standard spare parts with ordering information.	
9.5	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.	
10	Timelines	
10.1	Not Applicable	
11	Preferred list of Makes	
11.1	IKA, VELP Scientifica, Thermo, Spinix	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

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	Equipment Name	Vortex Mixer			
	Document No.	DS-VOM 02			
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Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
G1-VOM 01	Animal house	Lab area - Testing	G1G055	4700 X 7300	2700
G1-VOM 02	Animal house	Sample Preparation (Main Testing area)	G1G056	4700 X 5100	2700
G1-VOM 03	Animal house	Inoculation Area (Testing)	G1G057	4800 X 5100	2700
G1-VOM 04	Animal house	Sample Preparation (Challenge)	G1G079	4000 X 5000	2700
G1-VOM 05	Animal house	Inoculation Area (Challenge)	G1G080	2900 X 8200	2700
Q1-VOM 01	Admin, QA and QC	Instrumentation Lab	Q1S020	6500 X 3580	2400
Q1-VOM 02-03	Admin, QA and QC	Chemical Lab / Bio Chemistry	Q1S022	6240 X 7350	2400
Q1-VOM 05	Admin, QA and QC	Rabies/JE BSC + Titration + Advent	Q1S037	2400 X 5200	2400
Q1-VOM 06	Admin, QA and QC	Measles BSC + Titration + Advent	Q1S039	3600 X 3440	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
10-02-2014	Ms. Niharika Ruhela	00	-	s	
Table-3: Annexure					
Not applicable					