

Equipment Specification Data Sheet

Equipment Name: Automatic Media
Preparator with pourer

Document No.: DS-AMP 01

Revision: 00

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
Q1	Admin, QA & QC	Q1-AMP 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
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Prepared by

Mr. Tushar Shinde	Process Engineer		11/02/2016
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Checked by

Mr. Yogesha M J	Process Engineer		11-02-2016
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Approved by

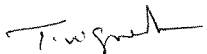
Dr. Harshad Mali	Lead Engineer - Process		11/02/2016
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HLL Biotech Limited


Name	Designation	Signature	Date
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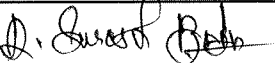
Reviewed by

User department: SANGEETHA K. R.	Manager		15/02/2016
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Project / Engineering department VIGNESH KARAN	DM-PROJECTS		15/2/16
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Approved by

Head of the department V. SIVAKANESH	Manager		15/02/2016
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Head of the department (QA) D. Suresh Babu	DM-QA & QA		17.02.2016
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Authorized by

Project Authority K. R.	C.E.O.		19-2-16
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Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Automatic Media Preparator with pourer
	Project #	120310
	Document #	DS-AMP 01
		
1 Process requirements		
1.1	This equipment is used for automatic preparation of media and pouring in plates	
2 Equipment ID		
2.1		
3 Technical Specification		
3.1	Model	cGMP with CE marking
3.2	Type	Fully automated
3.3	Accessories required	As per vendor spec
3.4	Quantity	01 nos
3.5	Dimension	As per vendor spec
3.6	Weight	As per vendor spec
3.7	Power requirement	As per vendor spec
3.8	capacity	55 and 90mm plates
3.9	Plates/hour	not less than 600 plates
3.10	Sterility temperature	95-125°C
3.11	Sterilization Time	60 minutes
3.12	Sterilization accuracy	Accuracy of temperature during sterilization 1 degree C
3.12	Dispensing Temperature	25-85°C
3.13	Probe	Temperature probe should be available
3.14	Printer	Should be available to export the details of prepared medium
3.15	Communication	User interface should display the information and able to store 25 programs
4 Material of Construction		
4.1	Outer Body	Vendor to specify
5 Specific Equipment requirement		
5.1	Supplement should be added during the process	
5.2	Transparent Lid to see all compounds from the top of the system	
5.3	Low running cost & operational flexibility	
5.4	Continuous stirring of medium during the complete cycle.	
5.5	The speed of the dispensing should be stable	

5.6	Temperature graphing shall be available throughout the cycle
5.7	The pourer stacker should possess both 90mm and 55mm plates
5.8	During the cycle the number of dishes and volume to be processed is count down and should displayed on the screen
6 Other requirement	
6.1	The equipment should be easy to use and clean.
7 Regulatory guidelines / standards	
7.1	System should comply 21 CFR part 11 compliance
7.2	The equipment shall be as per cGLP standards.
8 Safety requirements	
8.1	Vendor to specify
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	Operation and maintenance manuals
9.2	One year Warranty letter.
9.3	List of standard spare parts with ordering information.
9.4	Training for the technical persons to be included to handle the equipment.
10 Timelines	
Not Applicable	
NOTE: Accurate size and technical specification need to be mentioned by the vendor	
11 Preferred list of Make	
BIOMERIEUX, INTEGRA	

TABLE NO: 1

Equipment ID	Block Name	Room Name	Room No	Room Dimension	Room Height in mm
Q1-AMP 01	Admin, QA & QC	Media Preparation room	Q1S052	-	-

Table-2: Change Log

Date	Name	Revision	Section	Change/Comment
10-02-2015	Sandeep Kumar	00	-	New document

Table-3: Annexure

Not applicable
