

Equipment Specification Data Sheet

Equipment Name: Automatic Media Preparator with pourer

Document No.: DS-AMP 01

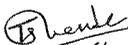
Revision: 00

Project No.: 120310

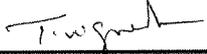
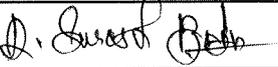
Project Name: Integrated Vaccines Complex, Chengalpattu

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

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
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Checked by			
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Approved by			
Dr. Harshad Mali	Lead Engineer - Process		11/02/2016

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
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Head of the department (QA)	DM-QC & QA		17.02.2016
Authorized by			
Project Authority RAMAN K. R.	C.E.O.		19-2-16

Equipment Specification Data Sheet

HLL Biotech Limited, Chennai

ne 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	<i>As per vendor spec</i>
3.4	Quantity	01 nos
3.5	Dimension	<i>As per vendor spec</i>
3.6	Weight	<i>As per vendor spec</i>
3.7	Power requirement	<i>As per vendor spec</i>
3.8	capacity	<i>55 and 90mm plates</i>
3.9	Plates/hour	<i>not less than 600 plates</i>
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
