

nne pharma®



Equipment Specification Data Sheet

Equipment Name: Colony Counter (Automatic)

Document No.: DS-CCR 02

Revision: 01

Project No.: 120310

Project Name: Integrated Vaccines Complex, Chengalpattu

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

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
<b>Prepared by</b>			
Mr. Sandeep Kumar	Process Engineer	<i>Sandeep</i>	26.02.2016
<b>Checked by</b>			
Mr. Yogesha M J	Process Engineer	<i>Yogesha M J</i>	26.02.2016
<b>Approved by</b>			
Dr. Harshad Mali	Lead Engineer - Process	<i>HML</i>	26.02.2016

HLL Biotech Limited

Name	Designation	Signature	Date
<b>Reviewed by</b>			
Head of department Quality Control <i>SANDEEP KUMAR</i>	Manager	<i>Sik</i>	01.03.2016
Project / Engineering Department <i>VIGNESH KARAN</i>	DM - PROJECTS	<i>Vignesh</i>	29.02.16
<b>Approved by</b>			
Head of the department Quality Control <i>V. Sivaganesh</i>	Manager	<i>V. Sivaganesh</i>	01.03.16
Head of the department <i>A. Durgesh Babu</i>	DM	<i>A. Durgesh Babu</i>	04.03.16
<b>Authorized by</b>			
Project Authority <i>Raman K. R.</i>	C-E-O	<i>Raman</i>	7-3-16

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
Equipment Name	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Colony Counter ( Automatic)
	Document No.	DS-CCR 02
	Revision No.	01
		
<b>1</b>	<b>Process requirements</b>	
1.1	This equipment is used for reading the bacterial colonies	
<b>2</b>	<b>Equipment ID</b>	
2.1	Q1-CCR 01	
<b>3</b>	<b>Technical Specification</b>	
3.1	Model	cGMP
3.2	Type	Desktop model SS
3.3	Accessories Required	As per vendor specification
3.4	Camera with Pixel	Vendor to specify
3.5	Lighting	6 combinations, top and bottom light, white or black background
3.6	Colony Identification	Minimum size of detected colony 0.1mm
3.7	Quantity	1 no
3.8	Type	Fully automatic
3.9	Software	Vendor to specify
3.10	Plate formats	Plates upto 50-90 mm
3.11	Data base	Data base to store all data and images
<b>4</b>	<b>Material of Construction</b>	
4.1	Body	SS 304 or powder coated
<b>5</b>	<b>Specific Equipment requirement</b>	
5.1	Generate fast automatic and accurate colony with detail statistics	
5.2	CCD camera with Digital zoom	
5.3	Long lasting LED lightings	
5.4	Automatic Archiving and printing of Data	
5.5	Automatic settings for more than 20 preset media	
5.6	Brightness, contrast and sensitivity automatically by the software	
5.7	User friendly software	

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5.8	Export data to Excel,PDF	
5.9	The equipment shall be able to withstand the mechanical stresses	
5.10	Equipment should be compatible for cleaning with all standard disinfectant	
5.11	Equipment should be provided with handle to carry from one place to other place easily	
<b>6</b>	<b>Other requirement</b>	
6.1	Training/Demo for the users on operation and cleaning to be provided.	
<b>7</b>	<b>Regulatory aspects</b>	
7.1	cGMP Complaint.	
<b>8</b>	<b>Safety requirements</b>	
	<b>Following facilities must be provided to protect personnel and equipment:</b>	
8.1	Proper earthing should be done.	
8.2	Appropriate closure of all parts.	
8.3	Password authentication for access.	
<b>9</b>	<b>Documents</b>	
	<b>Following documents, but not limited to these, must be provided by the vendor as part of the supply package in hard copy as well as editable electronic file.</b>	
9.1	IOQ Document.	
9.2	Operation and maintenance manuals 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	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their procedure.	
<b>10</b>	<b>Timelines</b>	
10.1	NA	
<b>11</b>	<b>Preferred list of Makes</b>	
11.1	Interscience (scan®),UVP colony Doc.	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

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Vaccine Pharmaplan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <b>HLL BIOTECH LIMITED</b> <small>(A Joint Venture of HLL Biotech Limited &amp; Government of Tamil Nadu)</small>		
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<b>Table-1: Equipment location</b>					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-CCR 01	Admin QA & QC	EMP Observation room	Q1S028	3850 X 2700	2400
<b>Table-2: Change Log</b>					
Date	Name	Revision	Section	Change/Comment	
18-02-2016	Sandeep Kumar	00	-	New document	
24-02-2016	Sandeep Kumar	01	-	Updated as per comments received from HBL on 22-02-2016	
<b>Table-3: Annexure</b>					
Not applicable					