

Equipment Specification Data Sheet

Equipment Name: Colony Counter  
(Automatic)

Document No.: DS-CCA 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-CCA-01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
<b>Prepared by</b>			
Mr. Kiran Kumar M S	Engineer - Process	<i>Kiran</i>	6/7/2015
<b>Checked by</b>			
Mr. Yogesha M J	Engineer - Process	<i>Yogesha-mj</i>	6/7/2015
<b>Approved by</b>			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines	<i>Vikas</i>	6/7/2015

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Equipment Name: Colony Counter  
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Project Name: Integrated Vaccines  
 Complex, Chengalpattu

HLL Biotech Limited



Name	Designation	Signature	Date
Reviewed by			
Suryesh Kumar . R	Manager		8/7/2015
Polina Sreenath	Deputy Manager		8/7/2015
Approved by			
Siva Ganesh . V	Manager		10/7/2015
Suresh babu . R	DGM		10/7/2015
Authorized by			
Ramas . k . Ramasubramanian	CFO		13/7/2015



Equipment Specification DataSheet			
HLL Biotech Limited, Chennai			
one pharma plan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HLL BIOTECH LIMITED Subsidiary of HLL Lifecare Limited A Government of India Enterprise
	Equipment Name	Colony counter (Automatic)	
	Document No	DS-CCA 01	
	Revision No	0	
1	Process Requirements		
1.1	This equipment is used for reading the bacterial colonies.		
2	Equipment ID		
2.1	Q1-CCA 01		
3	Technical Specification		
3.1	Model	cGMP	
3.2	Type	Desktop compact model SS	
3.3	Accessories required	As per vendor specification	
3.4	Camera with pixel	640x480 pixels	
3.5	Lighting	6 Combinations, top and bottom light, White or black back ground	
3.6	Colony identification	Minimum size of detected colony 0.1mm	
3.7	Quantity	1 no	
3.8	Type	Fully automatic	
3.9	Software	As per vendor specification	
3.10	Plate Formats	Plates up to 50-90mm	
3.11	Printer	Low cost print	
3.12	Database	Database that stores all data and images	
4	Material of Construction		
4.1	Outer Body	As per vendor specification	
5	Specific Equipment Requirments		
5.1	Generate fast automatic and accurate colony with detailed 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		
5.8	Export of 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	The equipment should be provided with handle to carry from one place to other place easily.		
6	Other Requirement		
6.1	Training / Demo for the users on operation and cleaning to be provided.		
7	Regulatory Aspects		
7.1	cGMP compliant		
8	Safety Requirements		
	Following facilities must be provided to protect personnel and equipment		
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, are expected from 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 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	Not Applicable
<b>11</b>	<b>Preferred list of Make</b>
11.1	Interscience ( scan), UVP colony Doc
	NOTE: Accurate size and technical specification need to be mentioned by the vendor



Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
	<b>INTEGRATED VACCINES COMPLEX, CHENGALPATTU</b>		 <b>HLL BIOTECH LIMITED</b> <small>Subsidiary of HLL Lifecare Limited (A Government of India Enterprise)</small>		
	Equipment Name	Colony Counter ( Automatic)			
	Document No.	DS-CCA-01			
	Revision No.	0			
<b>Table-1: Equipment location</b>					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-CCA- 01	Admin QA & QC	EMP Observation room	Q1S028	3850x2700	2400
<b>Table-2: Change Log</b>					
Date	Name	Revision	Section	Change/Comment	
11-08-2014	Kiran Kumar MS	00	-	New document	
<b>Table-3: Annexure</b>					
Not applicable					

**Equipment Specification Data Sheet**

**Equipment Name: Colony Counter  
(Manual)**




**Document No.: DS-CCM 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-CCM-01	-	2

NNE Pharmaplan India			
Name	Designation	Signature	Date
<b>Prepared by</b>			
Mr. Kiran Kumar M S	Engineer - Process		6/7/2015
<b>Checked by</b>			
Mr. Yogesha M J	Engineer - Process		6/7/2015
<b>Approved by</b>			
Mr. Vikas Katial	GM - Projects (SME) & Head COC Vaccines		6/7/2015

**Equipment Specification Data Sheet**

**Equipment Name: Colony Counter  
 (Manual)**


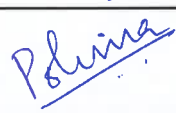


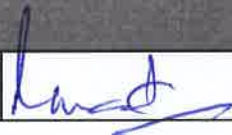
**Document No.: DS-CCM 01**


**Revision: 00**

**Project No.: 120310**

**Project Name : Integrated Vaccines Complex  
 Chengalpattu**


**HLL Biotech Limited**

Name	Designation	Signature	Date
<b>Reviewed by</b>			
Jayesh Kumar. R	Manager		8/7/15
Polina Sreenath	Deputy Manager		8/7/15
<b>Approved by</b>			
Siva Ganesh. V	Manager		10/7/15
Lunesh babu. R	DCM		10/7/15
<b>Authorized by</b>			
Raman. K. Rama Chandra	CEO		13/7/2015

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Colony Counter (Manual)
	Document No.	DS-CCM 01
	Revision No.	00
		
1	Process Requirements	
1.1	This equipment is used for counting bacterial colonies.	
2	Equipment ID	
2.1	Q1-CCM-01	
3	Technical Specification	
3.1	Type	Desktop compact model
3.2	Model	cGMP
3.3	Display	LED display with audio beep at every count
3.4	Accessories required	Pen, Magnifying lens ,power cord and lens holding rod
3.5	Magnification	2X
3.6	Maximum count	9999
3.7	Weight	Not more than 5 kg.
3.8	Traceability	Instant export of results via USB transfer
3.9	Dimensions	As per vendor specification
3.10	Quantity	2 nos
4	Material of Construction	
4.1	Outer Body	Full SS fabricated body shall be epoxy coated
5	Specific Equipment Requirements	
5.1	The model should have advanced sensors enables usage of any commercially available hard tipped marker pen	
5.2	The design of the equipment should ensures fast and accurate count	
5.3	The equipment shall be able to withstand the mechanical stresses.	
5.4	The equipment should be provided with handle to carry from one place to other place easily.	



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HLL Biotech Limited, Chennai		
HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Colony Counter ( Manual)
	Document No.	DS-CCM 01
	Revision No.	00
5.5	Equipment should be compatible for cleaning with all standard disinfectant.	
6	<b>Other Requirements</b>	
6.1	Training/Demo for the users on operation and cleaning to be provided.	
8	<b>Regulatory Aspects</b>	
8.1	The equipment shall be as per cGLP standards.	
9	<b>Safety Requirements</b>	
	Following facilities must be provided to protect personnel and equipment:	
9.1	Proper earthing should be done.	
9.2	Appropriate closure of all parts.	
9.3	Password authentication for access.	
10	<b>Documents</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.	
10.1	IOQ Document.	
10.2	Operation and maintenance manuals shall be provided along with IOQ documents during installation at site.	
10.3	Warranty letter for 1 year from the date of supply.	
10.4	Calibration certificates of critical instruments with respect to the traceable national reference standard instrument and their procedure.	
11	<b>Timelines</b>	
11.1	NA	
12	<b>Preferred list of Makes</b>	
12.1	INTEGRA, LAPIZ, HI MEDIA	
	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			 <small>HLL BIOTECH LIMITED Subsidiary of HLL Lifescare Limited A Government of India Enterprise</small>	
	Equipment Name	Colony Counter ( Manual)			
	Document No.	DS-CCM 01			
	Revision No.	00			
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