

**DATA SHEET**

**HLL BIOTECH LIMITED, CHENNAI**

<b>nne pharmaplan®</b>	<b>REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR</b>		 <b>HLL BIOTECH LIMITED</b> <small>(A Subsidiary of HLL Lifecare Limited)          (A Government of India Enterprise)</small>
	<b>Colony Counter</b>		
	<b>Project No :</b>	<b>110831</b>	
	<b>Document No:</b>	<b>DS-COC 01</b>	

**1 Equipment ID and Process requirements**

<b>1.1</b>	<b>Equipment ID</b>	<b>Process requirements</b>
<b>1.2</b>	M1-COC 01	It is used to count the microbial cell colonies

**2 Technical Specifications**

<b>2.1</b>	<b>Model</b>	GLP
<b>2.2</b>	<b>Type</b>	Automatic
<b>2.3</b>	<b>Type of light source</b>	LED lighting
<b>2.4</b>	<b>Image resolution</b>	Up to 4752 x 3168
<b>2.5</b>	<b>Minimum size of detected colony</b>	0.3 mm or <b>Vendor to specify</b>
<b>2.6</b>	<b>Camera</b>	An integral CCD colour camera.
<b>2.7</b>	<b>Measurement Time</b>	Up to 500 colonies per second.
<b>2.8</b>	<b>Detection</b>	Automatic with manual override.
<b>2.9</b>	<b>Counts on</b>	Petri dishes, Pour and Spiral plates
<b>2.10</b>	<b>Plate size (Max.)</b>	Up to max. 90 mm dia or <b>Vendor to specify</b>
<b>2.11</b>	<b>Traceability</b>	automatic saving and report printout of all data, images and results.
<b>2.12</b>	<b>Traceability formats</b>	Excel, JPEG, BMP and PDF
<b>2.13</b>	<b>Database</b>	MS SQL Server Express database automatically stores all data.
<b>2.14</b>	<b>Power supply</b>	vendor to specify
<b>2.15</b>	<b>Quantity</b>	1 no
<b>2.17</b>	<b>External Dimension (L x W x H) mm</b>	(250 x 270 x 250) or <b>Vendor to specify</b>

**3 Material Of Construction**

<b>3.1</b>	As per GMP compliances
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**4 Specific Requirements**

<b>4.1</b>	Colony counter should be automatically counts the cell colonies .
<b>4.2</b>	Colony counter must be portable and ergonomocally designed to minimize bench space required.
<b>4.3</b>	It should able to automatic adjustment of the counting area.
<b>4.4</b>	Colony counter should display the image on computer screen with counted colonies clearly marked. The zoom function allows the user to closely view plates, confirming accurate counting.
<b>4.5</b>	It should have automatic separation of clustered colonies.
<b>4.6</b>	An integral CCD colour camera should be able to adjusted to increase the sensitivity of the detection, enabling colonies as small as 0.3mm to be imaged and counted.
<b>4.7</b>	The LED lighting should be able to switched from upper to lower options, enabling counting on both light and dark media.
<b>4.8</b>	Software should use algorithm for colony counting on petri dishes, pour and spiral plates.
<b>4.9</b>	The software should be compatible with above stated colony counter.
<b>4.10</b>	Software should able to generate non-editable result sheet.
<b>4.11</b>	Software should meet 21 CFR Part 11 technical requirements.
<b>4.12</b>	Software should be provided with the colonu counter.

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**4.13 Minimum PC specification:**

- **Processor:** Intel Core 2 or Core i processor 2.13 GHz or better
- **Operating system:** Windows XP Professional 32 bit version or Windows 7 Professional 32 bit and 64 bit version
- **Monitor:** 1280 x 1024 minimum resolution (not comptabile with lower resolutions as some elements of the application become inaccessible)
- **Hard drive:** 160GB (or larger)
- **Graphics:** Intel X4500 or better
- **2Gb RAM** or better
- **CD-Rom drive** (required for software installation)
- **One main board USB 2 free port, One RS 232 free port with an RS 232 adapter**

**5 Other requirement**

- 5.1 Colony counter will operate under most normal condition but should not be exposed to moisture or extreme variation in temperature.
- 5.2 Equipment should be integrated with printer, to analyse result details.
- 5.3 On power failure equipment should come in fail safe condition.
- 5.4 Vendor shall provide more features apart from above.
- 5.5 Cleaning shall be able done manually.

**6 Regulatory aspects**

- 6.1 21 CFR Part11 Compliance.
- 6.2 RS 232 interface is required to transfer the data as well as to take the print out.
- 6.3 CE certicatcon

**7 Safety**

- 7.1 Proper earthing of the equipment.
- 7.2 Appropriate closure of all parts.

**8 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**
- 8.1 IOQ Protocol.
  - 8.2 Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
  - 8.3 Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
  - 8.4 All equipment warranty should be valid for one year from the date of completion.
  - 8.5 Vendor should provide list of standard spare parts with ordering information.
  - 8.6 Vendor should provide list of change parts (if applicable) with ordering information

**9 Timelines**

9.1 *Not Applicable*

**NOTE:** Accurate size and technical specification need to be mentioned by the vendor.

AFI Approved for Enquiry			AFO Approved for Ordering			
		<i>Megha</i>	<i>Pulm</i>			
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**Colony Counter**

**PROJECT No: 110831**

**DOCUMENT No : DS-COC 01**



**TABLE NO: 1**

<b>EQUIPMENT ID</b>	<b>Block Name</b>	<b>Room Name</b>	<b>Room No</b>	<b>Room dimension in mm</b>	<b>Room height in mm</b>
M1-COC 01	Sterility Media Preparation and Microbiology	Lab	M1G039	3020 x 5050	3000

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