

## DATA SHEET

HLL BIOTECH LIMITED, CHENNAI

nne pharmanplan

REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII,  
COONOR

Colony Counter

Project No : 110831

Document No: DS-COC 01



1	Equipment ID and Process requirements	
1.1	Equipment ID	Process requirements
1.2	M1-COC 01	It is used to count the microbial cell colonies
2	Technical Specifications	
2.1	Model	GLP
2.2	Type	Automatic
2.3	Type of light source	LED lighting
2.4	Image resolution	Up to 4752 x 3168
2.5	Minimum size of detected colony	0.3 mm or <b>Vendor to specify</b>
2.6	Camera	An integral CCD colour camera.
2.7	Measurement Time	Up to 500 colonies per second.
2.8	Detection	Automatic with manual override.
2.9	Counts on	Petri dishes, Pour and Spiral plates
2.10	Plate size (Max.)	Up to max. 90 mm dia or <b>Vendor to specify</b>
2.11	Traceability	automatic saving and report printout of all data, images and results.
2.12	Traceability formats	Excel, JPEG, BMP and PDF
2.13	Database	MS SQL Server Express database automatically stores all data.
2.14	Power supply	vendor to specify
2.15	Quantity	1 no
2.17	External Dimension (L x W x H) mm	(250 x 270 x 250) or <b>Vendor to specify</b>
3	Material Of Construction	
3.1	As per GMP compliances	
4	Specific Requirements	
4.1	Colony counter should be automatically counts the cell colonies .	
4.2	Colony counter must be portable and ergonomocally designed to minimize bench space required.	
4.3	It should able to automatic adjustment of the counting area.	
4.4	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.	
4.5	It should have automatic separation of clustered colonies.	
4.6	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.	
4.7	The LED lighting should be able to switched from upper to lower options, enabling counting on both light and dark media.	
4.8	Software should use algorithm for colony counting on petri dishes, pour and spiral plates.	
4.9	The software should be compatible with above stated colony counter.	
4.10	Software should able to generate non-editable result sheet.	
4.11	Software should meet 21 CFR Part 11 technical requirements.	
4.12	Software should be provided with the colonu counter.	

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4.13	<b>Minimum PC specification:</b> ■ <b>Processor:</b> Intel Core 2 or Core i processor 2.13 GHz or better ■ <b>Operating system:</b> Windows XP Professional 32 bit version or Windows 7 Professional 32 bit and 64 bit version ■ <b>Monitor:</b> 1280 x 1024 minimum resolution (not compatible with lower resolutions as some elements of the application become inaccessible) ■ <b>Hard drive:</b> 160GB (or larger) ■ <b>Graphics:</b> 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					
	<b>5 Other requirement</b>					
	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.					
<b>6 Regulatory aspects</b>						
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 certification					
<b>7 Safety</b>						
7.1	Proper earthing of the equipment.					
7.2	Appropriate closure of all parts.					
<b>8 Documents</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						
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					
<b>9 Timelines</b>						
9.1	Not Applicable					
<b>NOTE:</b> Accurate size and technical specification need to be mentioned by the vendor.						
AFI Approved for Enquiry			AFO Approved for Ordering			
		<i>mele</i>	<i>Pulm</i>			
01	09-09-2015	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	
				Sheet 1/2		

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TABLE NO: 1

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

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

AFI Approved for Enquiry

AFO Approved for Ordering

01	09-09-2015	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 2/2