

**DATA SHEET**

**HLL BIOTECH LIMITED, CHENNAI**

**REVIVAL OF DPT VACCINE MANUFACTURING FACILITY, PII, COONOR**

**hne pharmaplan**

**Binocular Microscope**

Project **110831**

EQUIPMENT ID **Annexure 1**

Document **DS-CMC-01**



<b>1</b>	<b>Process requirements</b>	
1.1	It is used to analyse the various types of microbiological samples.	
<b>2</b>	<b>Technical Specification</b>	
2.1	Model	cGLP Compliant; Clean Room Compliant
2.2	Type	Binocular compound microscope.
2.3	Performance requirement	Must meet all applicable regulatory/pharmacopeial requirements so that equipment and its component performs to ensure accuracy and reproducibility in test results
2.4	Display	NA
2.5	Dimensions	Vendor to specify
2.6	Power required	Vendor to specify
<b>3</b>	<b>Material of Construction</b>	
3.1	Body	Ergonomic body with stain and particle resistant finish.
<b>4</b>	<b>Specific Equipment requirement</b>	
4.1	Binocular head should rotate 360° and inclined at 30°. Features interpupillary and dioptic adjustment.	
4.2	Minimum magnification of the microscope should be 10X	
4.3	Nose piece position should be, reversed, extra-large, ball-bearing nose piece with a wide, knurled grip for easy operation. Features must be high-grade smooth operation and with positive click stops.	
4.4	Stage should be delivering a high level of fluid motion control and longevity. Motion must be controlled with a right-hand low-position coaxial control and it should be driven by a rack and pinion system.	
4.5	Focusing movement should be coaxial, low-position coarse and fine focus controls; it should be graduated to 2 microns per division; fitted with safety autostop. Range should be ± 20mm	
4.6	Refractive error should be +/- 5D left eyepiece.	
4.7	Working distance should be auxiliary objective to object distance 270 mm	
4.8	The microscope should have two focusing knobs mounted together. The large knob should be for coarse focus adjustment. The smaller knob should be for fine focus adjustment.	
4.9	Condenser: Bright field, Abbe N.A. 1.25 with iris diaphragm and swing out filter holder which shall be moved through rack pinion. The condenser unit to incorporate high efficiency optical system for optimum utilization of light from low to high magnification.	
4.10	The diaphragm should be wide open and must be able to pass light through the condenser.	
4.11	The diaphragm should be opened just enough to allow the objective lens to collect all of the light that should comes through the sample.	
4.12	Should be able to generate the report for each test on demand.	
4.13	Eyepiece eyecup with a low brightness level should be provided in order to suppress light reflection.	
4.14	All bolts, nuts on the exterior part of the equipment should be with cup head or cup nut.	
4.15	20 W lamp for illumination shall be provided	
<b>5</b>	<b>Other requirement</b>	
5.1	The instrument must be portable	
5.2	Design of the equipment should enhance cleaning by providing minimum sharp corners.	
5.3	Dust cover for nosepiece and dust cover for eyepiece tube should be provided to cover unused instrument openings.	
5.4	Cleaning cloth / paper should be provided to clean optical surfaces.	
5.5	Optional Accessories:Co-Axial mechanical stage, wooden storing cabinet with lock and key. Draw tube, spare objectives, sub-stage 20W Lamp for 220/110V.	

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	<b>Binocular Microscope</b>		
	Project	110831	
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	Document	DS-CMC-01	

**6 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</b>	
6.1	IOQ Protocol.
6.2	Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
6.3	Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
6.4	All equipment warranty should be valid for one year from the date of completion.
6.5	Vendor should provide list of standard spare parts with ordering information.
6.6	Vendor should provide list of change parts (if applicable) with ordering information

**7 Timelines**

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>			
01	09-09-2015	MGGP	PULM	<input type="checkbox"/>	<input type="checkbox"/>	
Rev	Date	Completed By	Checked By	AFI	AFO	Sheet 1 / 1

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	<b>Binocular Microscope</b>		
	<b>Project No :</b>	<b>110831</b>	
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**Annexure: 1**

Equipment ID	Block Name	Quantity	Room Name	Room No	Room dimension in mm	Room height in mm
B1-CMC 01	Diphtheria Block	1	IPQC	B1G057	2200 x 3310	3000
B1-CMC 02	Pertussis Block	1	IPQC	B1G018	2200 x 3310	3000
B2-CMC 03	Tetanus Block	1	IPQC	B2G026	3200 x 5335	3000
M1-CMC 01	Sterile Media Preparation and Microbiology	1	Lab	M1G039	3020 x 5050	3000
A2-CMC 01	Animal Experiment Block	1	Histopathology+Microbiology Room	A2G019	6250 x 2350	3000
A1-CMC 01	Animal Breeding	1	Animal Health Monitor	A1F014	2850 x 5215	2700

	<b>AFI Approved for Enquiry</b>		<b>AFO Approved for Ordering</b>			Sheet 2/2
		<i>Megle</i>	<i>Reevis</i>			
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