

Equipment Specification Data Sheet

Equipment Name: Upright Microscope

Document No.: DS-UMC 01




Revision: 03

Project No.: 120310

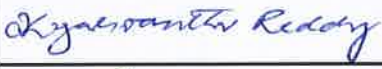


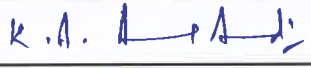


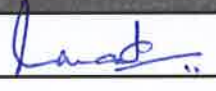
Project Name: Integrated Vaccines Complex,
Chengalpattu


Block Code	Block Name	Identification No.	Capacity	Quantity
G1	Animal House	G1-UMC 01	-	1
B4	Rabies Bulk	B4-UMC 01	-	1


NNE Pharmaplan India Limited


Name	Designation	Signature	Date
Prepared by			
Mr. Kiran Kumar M S	Engineer - Process		
Checked by			
Ms. Shilpa Rao	Senior Engineer - Process		
Approved by			
Mr. Vikas Katial	GM - Projects(SME) & Head COC Vaccines		

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
K. YASWANATH REDDY	Deputy Manager		15/6/15
P. NAVIN KUMAR	DEPUTY MANAGER (VIRAL VACCINES)		15/6/15
Polina Sreenath	Deputy Manager		12/6/15
Approved by			
Dr. K. A. AROOL ANAND	MANAGER		19/6/15
V. Sivaraman	Manager		19/6/15
Dr. Suresh Babu	DM		22/6/15
Authorized by			
Raman K. Ramachandran	CEO		24/6/15

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharmanplan*	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 <small>HLL BIOTECH LIMITED 22 Seelankar Road, Chennai - 600 061 (A Government of India Enterprise)</small>
	Equipment Name	Upright Microscope	
	Document No.	DS-UMC 01	
	Revision No.	03	
1	Process Requirements		
1.1	G1-UMC 01 : Used to visualize and identify (under magnification) various types of microorganisms.		
1.2	B4-UMC 01: Used for observing T25 cell culture flasks and cell count using hemocytometer.		
2	Equipment ID		
2.1	G1-UMC 01		
2.2	B4-UMC 01		
3	Technical Specifications		
3.1	Model	NA	
3.2	Type	Binocular compound microscope with camera provision	
3.3	Optical system	Infinity Corrected system	
3.4	Interpupillary distance adjustment	46mm to 75mm	
3.5	Quantity	2 No's	
3.6	Dimensions	Vendor to specify	
3.7	Power requirement	To be compatible to standard Indian Power supply sockets.	
3.8	Light Source	White LED	
4	Material of Construction		
4.1	Body	Ergonomic body with stain and particle resistant finish.	
5	Specific Equipment Requirements		
5.1	Nose Piece should rotate 360° and Binocular head should be inclined at 30° to 45°.Features Interpupillary and dioptric adjustment.		
5.2	Magnification of the microscope should be 4X, 10X, 40X and 100X.		
5.3	Nose piece position should be reversed with knurled grip for easy operation. Should features smooth operation with positive click stops.		
5.4	Stage: Fixed plane stage with specimen holder and should be provided X and Y movement.		
5.5	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.		
5.6	Focusing movement should be coaxial, low-position coarse and fine focus controls; it should be graduated to 2 microns per division; fitted with safety auto stop. Range should be ± 20mm		
5.7	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.		
5.8	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.		
5.9	Holders: 35mm diameter petri dish holder, universal holder, glass slide holder, hemocytometer holder.		
5.10	All external parts of the microscope should be disinfectable.		
5.11	Eyepiece eyecup with a low brightness level should be provided in order to suppress light reflection.		
5.12	White LED lamp for illumination shall be provided		

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Upright Microscope
	Document No.	DS-UMC 01
	Revision No.	03
		
6	Other Requirements	
6.1	The instrument must be portable.	
6.2	Dust cover for nosepiece and dust cover for eyepiece tube should be provided to cover when equipment not in use.	
6.3	Cleaning cloth / paper should be provided to clean optical surfaces.	
6.4	Accessories to be provided: Co-Axial mechanical stage, Draw tube, spare objectives, sub-stage with LED.	
6.5	Training /Demo for the users on operation and cleaning to be provided.	
7	Regulatory Aspects	
7.1	CE certification.	
8	Safety Requirements	
	Following facilities must be provided to protect personnel and equipment:	
8.1	Appropriate closure of all parts.	
8.2	Proper earthing is necessary.	
9	Documents	
	Following documents, but not limited to these, should be supplied by the vendor as part of the supply package in hard copy as well as editable electronic file	
9.1	IOQ documents.	
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 certificate of critical instruments with respect to traceable national reference standard instruments and their calibration procedure.	
10	Timelines	
10.1	NA	
11	Preferred list of Makes	
11.1	Leica, Zeiss, Nikon, Olympus.	
	NOTE: Accurate size and technical specification need to be mentioned by the vendor	

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
HLL Biotech Limited Integrated Vaccines Complex, Chengalpattu	INTEGRATED VACCINES COMPLEX, CHENGALPATTU				
	Equipment Name	Upright Microscope			
	Document No.	DS-UMC 01			
	Revision No.	03			
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
G1-UMC-01	Animal House	Lab Area (Challenge)	G1G078	4000×5000	2700
B4-UMC-01	Rabies Bulk	Cell Lab - 1	B4G038	5900×4850	3000
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
07-03-2014	Kiran Kumar M S	00	-	New document	
27-10-2014	Kiran Kumar M S	01	All	Updated as per comments received from HBL dated 10-10-2014	
07-01-2015	Kiran Kumar M S	02	All	Updated as per comments given by HBL team during meeting dated 07-01-2015 at HBL office	
06-05-2015	Kiran Kumar M S	03	All	Updated as per comments received from HBL dated 27-02-2015	
Table-3: Annexure					
Not applicable					

Equipment Specification Data Sheet

Equipment Name: Inverted Microscope

Document No.: DS-IMC 01




Revision: 03

Project No.: 120310

Project Name: Integrated Vaccines Complex,
Chengalpattu

Block Code	Block Name	Identification No.	Capacity	Quantity
B4	Rabies Bulk	B4-IMC 01	-	1
B4	Rabies Bulk	B4-IMC 02	-	1
Q1	Admin QA&QC	Q1-IMC 01	-	1

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Kiran Kumar M S	Engineer - Process		8/6/15
Checked by			
Ms. Shilpa Rao	Senior Engineer - Process		8/6/15
Approved by			
Mr. Vikas Katial	GM - Projects(SME) & Head COC Vaccines		9/6/15

Equipment Specification Data Sheet

Equipment Name: Inverted Microscope








Document No.: DS-IMC 01


Revision: 03


Project No.: 120310


Project Name: Integrated Vaccines Complex,
Chengalpattu


HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
P. NAVIN KUMAR	DEPUTY MANAGER (VIRAL VACCINE)		15/6/15
Saujeer Kumar R	Manager		12/6/15
Polina Sreenath	Deputy Manager		12/6/15
Approved by			
Dr. Juliet Selvi	Head - Viral Vaccine		20/6/15
V. Sivaraman	Manager		19/6/15
Dr. Surendra Babu	DM		22/6/15
Authorized by			
Raman K. Ramachandra	CEO		24/6/15

Equipment Specification Data Sheet		
HLL Biotech Limited, Chennai		
nne pharmaplan®	INTEGRATED VACCINES COMPLEX, CHENGALPATTU	
	Equipment Name	Inverted Microscope
	Document No.	DS-IMC 01
	Revision No.	03
		
1	Process requirements	
1.1	It is used for observing hemocytometer, 96 well plate, cell culture flasks, roller culture bottles and 10 layered cell factories/cell stacks	
2	Equipment ID	
2.1	B4-IMC 01	
2.2	B4-IMC 02	
2.3	Q1-IMC 01	
3	Technical Specification	
3.1	Model	NA
3.2	Type	Inverted microscope (Binocular)
3.3	Optical System	Infinity corrected system
3.4	Noise Pieces	Quadruple(Minimum)
3.5	Eye pieces (F.O.V)	10X
3.6	Magnification	4X to 40X
3.7	Condensers	Working Distance 72 mm to 80 mm.
3.8	Contrast Methods	Bright field,Phase Contrast.
3.9	Quantity	3 Nos.
3.10	Power requirement	To be compatible with standard Indian power supply sockets.
4	Material of Construction	
4.1	Body	Ergonomic body with stain and particle resistant finish.
5	Specific Equipment Requirements	
5.1	Binocular head should rotate 360° and inclined at 30° to 45°. Features interpupillary and dioptic adjustment.	
5.2	Minimum magnification of the microscope should be 4X.	
5.3	<p>The following specification should be provided :</p> <p>a) Illumination light - white LED/ Halogen.</p> <p>b) Focussing: Coaxial coarse/fine focusing.</p> <p>c) Tubes: Binocular tube (within main body).</p> <p>d) Holders: Petri Dish Holder, Universal Holder, Terasaki Holder ,Slide Glass Holder, Hemocytometer Holder.</p> <p>Stage: Fixed Plane stage and attachable mechanical stage to be provided and should have X and Y movement.</p> <p>e) the inverted microscope should be capable for observing cell culture flasks (T25,T75 and T175) roller culture bottles (850 cm² bottles with 110mm diameter) and 10 layered cell factories/cell stacks (Height = 19 cms) 96 well plate.</p> <p>f) All external parts of the microscope should be disinfectable.</p>	

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
HLL Biotech Limited	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HLL BIOTECH LIMITED <small>(Subsidiary of HLL Life Sciences Limited) (A Government of India Enterprise)</small>
	Equipment Name	Inverted Microscope	
	Document No.	DS-IMC 01	
	Revision No.	03	
5.4	Nose piece position should be, reversed, knurled grip for easy operation. Should feature smooth operation and with positive click stops.		
5.5	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.		
5.6	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.		
5.7	Eyepiece eyecup with a low brightness level should be provided in order to suppress light reflection.		
5.8	Provision for Camera attachment should be provided.		
5.9	Provision for epi fluorescence attachment should be provided.		
5.10	Equipment shall be compatible for cleaning with all standard disinfectants.		
6	Other Requirements		
6.1	The instrument must be portable.		
6.2	Dust cover for nosepiece and dust cover for eyepiece tube should be provided to cover the equipment when not in use.		
6.3	Cleaning cloth / paper should be provided to clean optical surfaces.		
6.4	Accessories to be provided :Spare Fuses, Draw tube, spare objectives, sub-stage white LED Lamp.		
6.5	Training /Demo for users on operation and cleaning to be provided.		
7	Regulatory aspects		
7.1	CE certification		
8	Safety requirements		
	Following facilities must be provided to protect personnel and equipment:		
8.1	Appropriate closure of all parts.		
8.2	Proper earthing is necessary.		
9	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.		
9.1	IOQ documents.		
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 certificate of critical instrument with respect to the traceable national reference standard instrument and their calibration procedure.		
10	Timelines		
10.1	Not Applicable		

Equipment Specification Data Sheet			
HLL Biotech Limited, Chennai			
nne pharma plan	INTEGRATED VACCINES COMPLEX, CHENGALPATTU		 HLL BIOTECH LIMITED <small>(Subsidiary of HLL Life Sciences Limited) (A Government of India Enterprise)</small>
	Equipment Name	Inverted Microscope	
	Document No.	DS-IMC 01	
	Revision No.	03	
11	Preferred list of Makes		
11.1	Leica, Zeiss, Nikon, Olympus		
	NOTE: Accurate size and technical specification need to be mentioned by the vendor.		

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
Vaccine Development	INTEGRATED VACCINES COMPLEX, CHENGALPATTU			 HLL BIOTECH LIMITED <small>(Subsidiary of HLL (Private) Limited) (A Government of India Enterprise)</small>	
	Equipment Name	Inverted Microscope			
	Document No.	DS-IMC 01			
	Revision No.	03			
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
B4-IMC 01	Rabies Bulk	Cell Lab - 2	B4G038	5900×4850	2700
B4-IMC 02	Rabies Bulk	Virus Seed Lab	B4G048	4700×2950	2700
Q1-IMC 01	Admin QA&QC	Cell culture area	Q1S069	2700×6510	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
07-03-2014	Kiran Kumar M S	00	-	New document	
27-10-2014	Kiran Kumar M S	01	All	Updated as per comments received from HBL dated 10-10-2014	
07-01-2015	Kiran Kumar M S	02	All	Updated as per comments given by HBL team during meeting dated 07-01-2015 at HBL office	
06-05-2015	Kiran Kumar M S	03	All	Updated as per comments received from HBL dated 27-02-2015	
Table-3: Annexure					
Not applicable					

Equipment Specification Data Sheet

Equipment Name: Fluorescence
Microscope

Document No.: DS-FMC 01

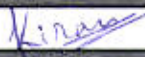
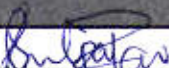

Revision: 03

Project No.: 120310


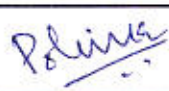


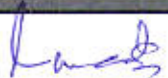
Project Name: Integrated Vaccines
Complex, Chengalpattu

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

NNE Pharmaplan India Limited

Name	Designation	Signature	Date
Prepared by			
Mr. Kiran Kumar M S	Engineer - Process		8/6/15
Checked by			
Ms. Shilpa Rao	Senior Engineer - Process		8/6/15
Approved by			
Mr. Vikas Katial	GM - Projects (SME) & Head of COC Vaccines		9/6/15

HLL Biotech Limited

Name	Designation	Signature	Date
Reviewed by			
Sanjeevkumar. R	Manager		12/6/15
Polina Sreenath	Deputy Manager		12/6/15
Approved by			
V. Sivaganesh	Manager		19/6/15
D. Supreth Babu	Deputy		22/6/15
Authorized by			
Raman. K. Ramachandran	CEO		24/6/15

Equipment Specification Data Sheet

HLL Biotech Limited, Chennai

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

nne pharmaplan

Equipment Name

Fluorescence Microscope

Document No

DS-FMC 01

Revision No.

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1 Process Requirement

- 1.1 It is used to analyse the various types of microbiological samples. Microscopes with an inverted-style frame are designed primarily for tissue culture applications and are capable of producing fluorescence illumination through an episcopic and optical pathway.

2 Equipment ID

- 2.1 Q1-FMC 01

3 Technical Specification

- | | | |
|------|----------------------------|---|
| 3.1 | Model | NA |
| 3.2 | Type | Fluorescence microscope (Binocular) |
| 3.3 | Optical system | Infinity Corrected system |
| 3.4 | Noise Pieces type | Sextopule |
| 3.5 | Eye pieces (F.O.V) | 10X / 23mm or better |
| 3.6 | Magnification | 4X to 40X and More |
| 3.7 | Interpupillary Distance | 48mm to 75 mm |
| 3.8 | Fluorescence filter turret | 6 position or better |
| 3.9 | Fluro chrome | FITC, DAPI, TRITC, etc |
| 3.10 | Contrast methods | Bright field, phase contrast |
| 3.11 | light source | Transmitted Light - white LED / Halogen lamp, Fluorescence light - Mercury lamp (100W) |
| 3.12 | Objective | Fluorite/Semi apochromatic long working objective 4X, 10X, 20X and 40X |
| 3.13 | Quantity | 1 No. |
| 3.14 | Power required | To be compatible to standard Indian Power supply socket |
| 3.15 | PC and Monitor | System to include PC suiting the application. The system should include high end PC for all the above applications. PC configuration should be capable of operating above mentioned software. |
| 3.16 | Camera | Dual mode high speed cooled camera with 5 mp in colour and 2.0 mp in monochrome mode or better |
| 3.17 | Operator Protection | Should have the arrangement to protect the operator from UV exposure. |

4 Material of Construction

- 4.1 Body Ergonomic body with stain and particle resistant finish, antimicrobial coated

5 Specific Equipment requirement

- 5.1 Nose piece position should be, reversed, with knurled grip for easy operation. Should be smooth operation and with positive click stops.

Equipment Specification Data Sheet

HLL Biotech Limited, Chennai

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

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Equipment Name

Fluorescence Microscope

Document No

DS-FMC 01

Revision No.

3



- 5.2 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.
- 5.3 Stage and Nose piece movement shall be motorized
- 5.4 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.
- 5.5 The fluorescence microscope should have provision for taking photos of the samples under analysis and should be compatible to be connected and viewed through PC. Microscope camera and software shall be offered from original equipment manufacturer for better synchronisation.
- 5.6 Eyepiece eyecup with a low brightness level should be provided in order to suppress light reflection.
- 5.7 Software should be compatible for multiple PC.
- 5.8 Equipment shall be compatible for cleaning with all standard disinfectants
- 6 Other Requirement**
- 6.1 The instrument must be portable
- 6.2 Design of the equipment should enhance cleaning by providing minimum sharp corners.
- 6.3 Dust cover for nosepiece and dust cover for eyepiece tube should be provided to cover unused instrument openings.
- 6.4 Cleaning cloth / paper should be provided to clean optical surfaces.
- 6.5 Optional Accessories: Co-Axial mechanical stage. Spare objectives, sub-stage Lamp for 220V.
- 6.6 Training/Demo for the users on operation and cleaning to be provided
- 7 Regulatory Aspects**
- 7.1 CE certification
- 8 Safety Requirements**
- Following facilities must be provided to protect personnel and Equipment**
- 8.1 Appropriate closure of all parts
- 8.2 Proper earthing is necessary
- 9 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
- 9.1 Operation and maintenance manuals shall be provided along with IQ and OQ documents during installation at site
- 9.2 IOQ documents
- 9.3 Warranty Letter for 1 year from the date of supply
- 9.4 Calibration certificate of critical instruments with respect to the traceable national reference standard instrument and their calibration procedure.
- 9.5 List of standard spare parts with ordering information.
- 9.6 List of change parts (if applicable) with ordering information

Equipment Specification Data Sheet

HLL Biotech Limited, Chennai

INTEGRATED VACCINES COMPLEX, CHENGALPATTU

Equipment Name

Fluorescence Microscope

Document No

DS-FMC 01

Revision No.

3

HBLHLL BIOTECH LIMITED
Subsidiary of HLL, Jaipur Limited
a Government of India Enterprise


10 Timeline

10.1 NA

11 Preferred List of Makes

11.1 Leica, Zeiss, Nikon, Olympus

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

Equipment Specification Data Sheet					
HLL Biotech Limited, Chennai					
nne pharmaplan™	INTEGRATED VACCINES COMPLEX,			 HBL HLL BIOTECH LIMITED <small>(a subsidiary of HLL Biotech Limited) (a Government of India Enterprise)</small>	
	Equipment Name	Fluorescence Microscope			
	Document No.	DS-FMC 01			
	Revision No.	03			
Table-1: Equipment location					
Equipment ID	Block Name	Room Name	Room No	Room dimension in mm	Room height in mm
Q1-FMC 01	Admin QA & QC	Virus Testing Labs	Q1S036	5450x2700	2400
Table-2: Change Log					
Date	Name	Revision	Section	Change/Comment	
12-03-2014	Kiran Kumar MS	00	-	New document	
27-10-2014	Kiran Kumar MS	01	All	Updated as per comments received from HBL dated 15-10-2014	
06-01-2015	Kiran Kumar MS	02	All	Updated as per comments given by HBL team during meeting dated 06-01-2015 at HBL office.	
30-04-2015	Kiran Kumar MS	03	All	Updated as per comments received from HBL dated 27-02-2015.	
Table-3: Annexure					
Not applicable					