

MICROBIOLOGY DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL FOR MICROSCOPE

Pre - Execution Approval

	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



PHARMA DEVILS MICROBIOLOGY DEPARTMENT

INSTALLATION QUALIFICATION PROTOCOL FOR MICROSCOPE

1.0 Objective:

The purpose of installation qualification is as follows

- To provide documented evidence that the mentioned Microscope is installed as per design.
- To ensure that the Microscope installed confirms to purchase specifications and manufacturer literature, and to document the information that the Microscope meets the specification.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	Microscope
ID Number	
Location	Incubator Room

3.0 Equipment / System Description:

The Microscope basically consists of combination of latest optical and mechanical advancement using the match pair of eyepieces to view the specimen through the spring-loaded objective of different magnification power.

The illuminated base and a removable NA 125 Abbe condenser is provided for the brighter illumination level and an iris diaphragm for resolution and contrast control.

The coarse and fine focusing is COAXIAL type for clear and sharp view of the specimen.

The latest application of CCD Camera with PC base imaging card system is also possible.

The Water Bath Chamber is made of stainless steel, which is properly sealed and insulated to prevent it from leakage.

The use of Microscope with different magnification power is to view the invisible micro organs for microbiological study.

The use of image analyzer is to save and store the image for authentication of record.



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4.0 Checklist for Preinstallation verification:

The purpose of the checklist is to confirm the availability of required documents for installation and to verify the availability of components and parts as per the approved purchase order in presence of the technical personnel of the vendor.

Preinstallation verification checklist is enclosed as Annexure - I.

5.0 Checklist for Installation verification:

Installation verification checklist is enclosed as Annexure - II.

6.0 Any Changes identified towards equipment design / lay out.

Refer Annexure - III.

7.0 Recommendations and Conclusions:

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8.0 References:

Copy of Purchase order

Packing list supplied by vendor (Not applicable).

List of spares (Not applicable).

Installation Qualification submitted by vendor.

Impact Assessment analysis.

9.0 Annexure

Annexure - I : Check list for Preinstallation Verification.
Annexure - II : Check list for Installation Verification.
Annexure - III : List of Changes / Deviation.
Annexure - IV : Installation Qualification Submitted by the vendor.
Annexure - V : Impact Assessment Analysis.
Annexure - VI : Summary Report of Installation Qualification
Annexure - VII : Copy of Purchase order



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10.0 Abbreviations:

IQ : Installation Qualification

Post execution approval:

	Name	Designation	Signature	Date
Compiled By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				



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Annexure - I

Checklist for Preinstallation Verification

S.No.	Main Components Accessories / Documents	Code / Doc No.	Actual	Remarks
1.	Purchase Order No.			
2.	Vendor's Name	Scientico Instruments		
3.	Instrument Make	Labovision		
4.	Instrument Model No.	Myscope Beta		
5.	Instrument Manual	Instrument Manual submitted by the vendor		



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Annexure - II

Checklist for Installation Verification

S.No.	System Data	Acceptance Criteria	Actual	Remarks
А.	Equipment /Instrument specific details			
1.	Light Source	Halogen Lamp 6 V - 20 watt should be provided		
2.	Observation	Binocular Head with 10 X to 18 X Eyepiece matched pair should be provided		
3.	Camera System	Inbuilt Digital Camera should be provided		
4.	Imaging System	Image Analyzing system with software on CD should be provided		
5.	Magnification Range	40 x ,10 x, 40 x, 100 x oil immersion should be provided		
		All the electrical connection is in function as per design		
6.	Control Panel Testing	Function of each part of the unit against its specified function should be satisfactory		



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S.No.	System Data	Acceptance Criteria	Actual	Remarks
А.	Equipment /Instrument specific details			
7.	Installation / Down loading of Image Analyzing Software	Installation / Down loading of Image Analyzing Software should be done satisfactory		
		Properly Mounted, Supported and connected		
		Major components are securely anchored and protected from shock		
		No observable physical damage		
7.	Verification	Sufficient Room Provided		
		Electrical connections have been done according to drawing		
		Required electric connections are tight, proofed and grounded		
		Equipment identification nameplate is visible		



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S.No.	System Data	Acceptance Criteria	Actual	Remarks
В.	Location suitability			
1.	Location	Should be installed In Incubator Room - II		
C.		Utiliti	es	
1.	Electrical Power Supply	230 Volts AC 50Hz 1 phase, supply should be provided		
D.		Safet	y	1
1.	Not Applicable	Not Applicable		
Е.	MOC Certificates			
1.	Not Applicable	Not Applicable		
F.	Calibration Certificates			1
1.	Calibration Certificates	Should be provided		
G.	Testing Certificates			
1.	Not Applicable	Not Applicable		
Н.	Drawing Details	Drawing No.		
1.	Not Applicable	Not Applicable		



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Annexure - III

List of Changes / Deviations

S.No.	Description of Change / Deviations	Justification based on impact analysis

Verified By:

Approved By:



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Annexure - VI

Summary Report of Installation Qualification

Checks	Observations (Yes / No)	Reviewed By Sign / Date
All test procedures executed and verified as per the protocol.		
All criteria set forth in the installation qualification were met.		
Deviation if any		

Summary:

Summary Report Prepared By: Date & Sign