



OPERATIONAL QUALIFICATION PROTOCOL FOR MICROSCOPE

Pre - Execution Approval

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



OPERATIONAL QUALIFICATION PROTOCOL FOR MICROSCOPE

1.0 Objective:

- To determine that the equipment operates according to specifications, and to record all relevant information's and data to demonstrate its functions as intended for.

2.0 Scope:

Scope is limited to the following

Equipment / System Name	Microscope
ID Number
Location	Incubator Room

3.0 Checklist for Operational verification:

Operation of Microscope is verified for the compliance with the critical parameters mentioned in the Functional Specification. Sequentially prepare the list of operating checks specifying critical parameters, perform them as per operating procedure as mentioned in the vender operating manual & document the same in the attached check list (Annexure - I).

4.0 Any Changes/Deviations identified during operating checks:

Refer Annexure – II

5.0 Identification & preparation of Standard Operating Procedures:

Prepared the SOP for operation, cleaning and calibration of Microscope using the actual feedback from the operation checks and vendor-operating manual. The preventive maintenance procedure and schedule shall be applicable as per Annual Maintenance Contract of QC Instrument.

<u>S. No.</u>	<u>SOP Title</u>	<u>SOP Number</u>
1.	Cleaning, Calibration and Operation Of Microscope

6.0 Training



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The List of QC (Microbiology) person trained during the operation qualification of Microscope is listed as per Annexure - III.

7.0 Recommendations and Conclusions:

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8.0 References:

- Installation Qualification
- Operating Manual submitted by the Vendor.

9.0 Annexure

- Annexure - I : Checklist for Operational Verification.
- Annexure - II : List of Changes / Deviation.
- Annexure - III : Training Detail

10.0 Abbreviations:

- SOP : Standard Operating Procedure
- QC : Quality Control

Post execution approval:

	Name	Designation	Signature	Date
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Annexure - I

Checklist for Operational Verification

S.No.	Operating Parameters	Function	Observation	Remarks
1.	'ON' switch on the Base	To start the power supply of instrument		
2.	Operation	Position the specimen area of the slide over the center of stage of aperture. Use the stage control knobs to move the specimen slide to the desired position		
		Looking through the binocular head, raise the stage by adjusting the coarse focus knob until an image appears. Focus as sharply as possible with the coarse focus knob		
		Adjust the focusing to sharpen the image in the center of the field of view		
		Use the fine knob for sharp and clear view of the image		



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S.No.	Operating Parameters	Function	Observation	Remarks
2.	Operation	Always do the focusing with lowest power objective and then to increase magnification by rotating the nosepiece in step up position of the objectives in higher number		
		When using objective of higher numerical aperture proper focusing of the abbe condenser is very important. Focus the abbe condenser by racking the condenser up and down movement as may required for evenly illuminate the field		
		Use the Light intensity regulator from low to high as you go from low magnification to high for obtaining the best result		



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S.No.	Operating Parameters	Function	Observation	Remarks
2.	Operation	<p>Use the light intensity regulator from low to high as you go from low magnification to high for obtaining the best result.</p> <p>View the specimen with each objective and view the result with all or desire magnification power</p>		
3.	Use of High Power Objective 100 x with oil immersion	Rotate the nosepiece to position the lowest power objective in light path		
		Place one drop of the immersion oil on the lighted area of the specimen slide. Prevent the air bubble or dust in the oil which may obstruct the image		
		Rotate the nosepiece to position the 100 x in the Light path		
		Lift up the stage with the coarse focus knob until the objective is in contact with the immersion oil		



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S.No.	Operating Parameters	Function	Observation	Remarks
3.	Use of High Power Objective 100 x with oil immersion	Focus the image using the fine focus knob for the result/view at high power magnification.		
		At end of every use of oil immersion, wipe off all traces of oil from the objective with a soft lens tissue to prevent the life of 100 x vision		
4.	Image Analyzing	The built in digital camera will automatically capture the microscopy image of the sample / slide and the same would be appeared on the PC monitor screen on use of the image analyzer		
		To run the program follow the following procedure		
		Click the START menu of the PC System		



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S.No.	Operating Parameters	Function	Observation	Remarks
4.	Image Analyzing	Select the program menu to enter in to the image analyzing program having title 'LABEX' - 2		
		Double click the 'LABEX' - 2 to enter in to the image analyzing program folder.		
		The program will appear on the screen with the MENU list of the program		
		Click the image capture to view the captured image of the slide on the screen.		
		This will show the captured image of the sample which may then be measured, count and view with different utilities provided in the program with the help of MENU buttons of respective program		



PHARMA DEVILS

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S.No.	Operating Parameters	Function	Observation	Remarks
4.	Image Analyzing	Each Image with their respective processing of measurement, particle counting, etc can be saved in memory under individual folder as may desired with the identifications at the option of the user.		
		The print out of the saved image and the report there of is possible whenever desired on any desk jet printer.		



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Annexure - II

List of Changes / Deviations

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

Verified By:

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Annexure - III

Training Detail

S.No.	Name of Trainee	Name of Trainer

Verified By:

Approved By: