OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

FOGGER MACHINE

EQUIPMENT ID. No.	
LOCATION	**Ampoule Line**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FOGGER MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR FOGGER MACHINE	PROTOCOL No.:

1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Fogger Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol cum Report is limited to qualification of **Fogger Machine (Make: ……..) (Capacity- 9.0 Liter)** installed in Ampoule Line.
- This Operational Qualification Protocol cum Report will define the methods and documentation used to perform OQ activity of Fogger Machine.
- Successful completion of this Operational Qualification Protocol cum Report will verify that Fogger Machine meet all acceptance criteria and ready for Performance Qualification.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, Approval and compilation of the operational Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Operational Qualification. • Monitoring of Operation Process. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • To Co-ordinate and support for execution of Operational Qualification study as per Protocol. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	• Review of Operational Qualification Protocol cum Report. • To co-ordinate and support Operational Qualification Activity. • Post Approval of Operational Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Fogger Machine
Equipment ID.	
Manufacturer's Name	YANTRA
Model No.	YANTRA 09
Capacity	9.0 Liter
Location of Installation	Ampoule Line

6.0 EQUIPEMENT DESCRIPTION:

YANTRA is used for atomizing light liquids into a high aerosol volume dry fog/ mist of consisting of ultra-fine droplets.

ULV is defined as the ultra-low volume application rate of chemical solution per units pace / surface area in aerosol state.

Low flow rate 45-50 ml / minute produces a dry fog and finer droplets (less than 1 micron) that float extensively and diffuse uniformly across the space and remains airborne for sufficient period of time.

The density of the liquid solution used can affect the size of the fog droplets produced. At a given flow lighter liquids low viscosity) generally make smaller droplets & fine fog than heavier liquid solutions.

7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- IQ Protocol cum Report.
- SOP for Operation & Cleaning of Fogger Machine.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing.

S. No.	DOCUMENT NAME	DOCUMENT / SOP NO.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE	VERIFIED BY (QA) SIGN/DATE
1.	IQ Protocol cum Report				
2.	SOP for Operation & Cleaning of Fogger Machine.				

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.2 Operational and Functional Checks:

Operate the Fogger Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

COMPONENT	FUNCTION	OBSERVATIONS Complies/ Non Compiles	OBSERVED BY (ENGINEERING) SIGN/DATE
Power cord three pin plug	Connect with the main supply socket		
Positioning Lock Set	Nozzle to be set at desired angle.		
Nipple for filling	Easily remove the nipple		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.3 Flow Rate And Dead Volume Determination:

Procedure:

- Check the empty weight of fogger machine and record in below mention observation sheet.
- Remove the nipple lid and pour the 2000 ml prepared solution for fogging.
- Check the final weight of fogger machine and record in below mention observation sheet.
- Lock the desired Position of nozzle & tighten the two knobs on the sides.
- Plug in machine power cord three pin plug to main supply socket
- Start the fogging for 5 minute and check the fogger machine weight after fogging.
- Same procedure shall be repeated two times.
- Start the fogging for 3 minute and check the fogger machine weight after fogging.
- Same procedure shall be repeated two times.
- Start the fogging for 1 minute and check the fogger machine weight after fogging.
- Same procedure shall be repeated till flow rate are maintained 50 ml/minute.
- Calculate the flow rate ml/min.
- Dead volume shall be considered up to the solution level where flow rate are maintained 50 ml/minute.

8.3.1 Observation sheet

Empty Weight of Fogger		**Volume consumed (Kg)**	**Flow rate (ml/min)**
Addition of Disinfectant			
Final Weight of Fogger Machine			
Weight after 5 Min			
Weight after 5 Min			
Weight after 5 Min			
Weight after 3 Min			
Weight after 3 Min			
Weight after 3 Min			
Weight after 1 Min			
Weight after 1 Min			
Weight after 1 Min			
Weight after 1 Min			
Weight after 1 Min			
Weight after 1 Min			
Weight after 1 Min			
Weight after 1 Min			
Weight after 1 Min			
Left over quantity in fogger machine			
Dead Volume Quantity	Left Over Quantity + Quantity consumed in last minute + Quantity consumed in second last minute for safer side =		
Recommended Dead Volume Quantity			

8.4 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted without problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Schedule - M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.
- Party Document

10.0 DOCUMENTS TO BE ATTACHED:

- Any other Relevant Documents.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
FGM	:	Fogger Machine
ID.	:	Identification
IQ	:	Installation Qualification
MOC	:	Material of Construction
No.	:	Number
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization

17.0 PROTOCOL POST -APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
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HEAD (PRODUCTION)			

APPROVED BY:

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HEAD (QUALITY ASSURANCE)			