



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
FOGGER MACHINE**

PROTOCOL No.:

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



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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)			



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2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Fogger Machine for **Ampoule Line**.
- To confirm that the equipment and its components are installed as per the specifications mentioned in the vendor document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this Installation Qualification Protocol cum Report is limited to qualification of Fogger Machine (**Make: YANTRA**) (**Capacity- 9.0 Liter**) to be installed in Ampoule Line.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Fogger Machine.



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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	<ul style="list-style-type: none">• Preparation, Review, Approval and Compilation of the Installation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Installation Qualification Activity.• Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of Installation Qualification Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Review of Installation Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Installation Qualification Protocol cum Report.• Co-ordination, execution and technical support in Fogger Machine Installation Qualification Activity.• Responsible for Trouble Shooting (if occurs during execution).• Post Review of Installation Qualification Protocol cum Report after Execution.



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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 EQUIPMENT 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 Documents:

- Technical specification of equipment.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

INSTALLATION CHECK	OBSERVATION Complies/ Non Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Check the proper mechanical installation of Fogger Machine.		
Check the proper electrical installation of Fogger Machine.		
Check the parts are working properly.		
Check the equipment is free from any defects.		
Check the finishing of machine parts.		

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

Inference:

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Reviewed By

(Manager QA)

Sign & Date:



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8.2 General Checks and Location Suitability:

INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION Complies/ Non Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Leveling	Should be properly balanced and leveled.		
Welding of Joints	Welding of joints should be without any welding burrs.		
Place of Installation	Ampoule Line.		

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

Inference:

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Reviewed By

(Manager QA)

Sign & Date:



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8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION Complies/ Non Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Name	Fogger Machine		
Model	YANTRA 09 (Electrically operated aerial fogging system)		
Weight Empty	10 kg		
Capacity of tank	09 Liter SS Tank		
Dimension (W X H X D)	535 mm(W) X 575 mm (H) X 335mm (D)		
Chemicals fogged	Biocides, Disinfectants, Pesticides, Insecticides, Fungicides.		
Droplet Size Tested	Sub-Micron (Less than 1 micron)		
Metering System	45-50 ml/ minute (medium fog)		

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

Inference:

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.....

Reviewed By

(Manager QA)

Sign & Date:



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8.4 MOC Verification List:

PARTS NAME	MATERIAL OF CONSTRUCTION	OBSERVATION Complies/ Non Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Solution Tank Set	Stainless Steel		
Tubing	Silicon		
Hardware, connectors	Stainless Steel		

**Checked By
(Production)
Sign/Date:**

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

Inference:

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**Reviewed By
(Manager QA)
Sign & Date:**

8.5 Utility Verification List:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION Complies/ Non Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Power Supply	220-240 V, 50/60 Hz, Single Phase Supply Full load current: 10 Amps		

**Checked By
(Production)
Sign/Date:**

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

Inference:

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**Reviewed By
(Manager QA)
Sign & Date:**



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8.6 Safety:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION Complies/ Non Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Noise Level	Below 80 dB		

**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 References is the following

- Party Document

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement.
- Any Other Relevant Document.

11.0 DEVIATION FROM PRE-DEFINED 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:

- db : Decibel
- DQ : Design Qualification
- GA : General Arrangement
- FGM : Fogger Machine
- ml : Milliliter
- IQ : Installation Qualification
- Kg : Kilogram
- MOC : Material of Construction
- SS : Stainless Steel



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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)			