



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
INLINE HOMOGENIZER**

PROTOCOL No.:

**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
INLINE HOMOGENIZER-12.5 HP**

EQUIPMENT ID. No.	
LOCATION	ORAL LIQUID 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 Inline Homogenizer for Liquid Line.
- To confirm that the equipment and its components are installed as per the specifications mentioned in the qualification document and other requirements given by supplier.

3.0 SCOPE:

- The scope of this Installation Qualification Protocol cum Report is limited to qualification of **Inline Homogenizer (Make:)** to be installed in Oral Liquid 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 Inline Homogenizer.

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. • To co-ordination with user 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.
Engineering	<ul style="list-style-type: none"> • Review of Installation Qualification Protocol cum Report. • To execution and technical support in Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution).



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5.0 EQUIPMENT DETAILS:

Equipment Name	INLINE HOMOGENIZER
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Gross Volume	5500 Ltr.
Working Volume	5000 Ltr.
Model No.	
Sr. No.	
Location of Installation	Liquid Line

6.0 SYSTEM DESCRIPTION:

Homogenizers are the device to form homogeneous solutions or dispersions of two different phases or even similar phases. For example, liquid - liquid mixing and dispersion, liquid – solid disintegration and dispersion, and liquid – gas dispersion.

The versatility built into this machine provides its users with new and more efficient approaches to traditional processing techniques. High-speed mechanical and hydraulic shear forces are the real key to the success of this machine. The close tolerance between the Rotor and Stator (in between 0.5 to 0.6 mm) generates a shearing action which ensures the materials being processed are subjected to thousands of shearing actions each minute.

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document.
- Technical specification of equipment.

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.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.



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7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

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 Inline Homogenizer.		
Check the proper electrical installation of Inline Homogenizer.		
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	Liquid Line		
Room Condition	General Room Conditions.		
Working space around the Equipment.	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

Checked By
(Production)
Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

Inference:

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Reviewed By
(Manager QA)
Sign/Date:

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION Complies/Non Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Equipment Name	Inline homogenizer		
Model No.			
Location of Installation	Liquid 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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8.4 DOCUMENT VERIFICATION:

DOCUMENT NAME	(ATTACHED/ NOT ATTACHED)	OBSERVED BY (ENGINEERING) SIGN/DATE

**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
Electrical Supply	Voltage : 415 V Hertz : 50 Hz Phase : 3 Phase		

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

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

Inference:

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

8.6 Safety:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION Complies/Non Complies	OBSERVED BY (ENGINEERING) SIGN/DATE
Start On/Off switch: To Stop the process immediately.	Should be provided for equipment and operator safety.		
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:**



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9.0 REFERENCES:

The Principle References is the following

- Qualification 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
- IQ : Installation Qualification
- MOC : Material of Construction
- KW : Kilowatt
- V : Voltage
- Hz : Hertz



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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)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			