OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
INLINE HOMOGENIZER–12.5 HP

EQUIPMENT ID. No.	
LOCATION	**ORAL LIQUID LINE**
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

PHARMA DEVILS	OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR INLINE HOMOGENIZER	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 Inline Homogenizer and to ensure that it produces desired Quality & rated output according to manufactures specifications.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol cum Report is limited to qualification of **Inline Homogenizer (Make: ……)** be installed in Oral Liquid Line.
- This Operational Qualification Protocol cum Report will define the methods and documentation used to perform OQ activity of Inline Homogenizer.
- Successful completion of this Operational Qualification Protocol cum Report will verify that Inline Homogenizer meet all acceptance criteria and ready for further activity.

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. • To co-ordination with user and Engineering to carryout Operational Qualification. • Monitoring of Operation Qualification activity. • Post Approval of Operational Qualification Protocol cum Report after Execution.
Production	• Review of Operational Qualification Protocol cum Report. • Execution of Operational Qualification study as per Protocol.
Engineering	• Review of Operational Qualification Protocol cum Report. • To co-ordination, execution and technical support in Operational Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution).

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.	GSKIH12.5
Sr. No.	
Location of Installation	Liquid Line

6.0 EQUIPEMENT 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:

S.No.	Document Name	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	IQ Protocol cum Report			
2.	Draft SOP for Operation & Cleaning of Inline Homogenizer			
3.	Draft SOP for Preventive Maintenance of Inline Homogenizer			

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.

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 Operational and Functional Checks:

Operate the Inline Homogenizer 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 Button	• Use to turn the power ON or OFF. • Push again and power goes ON or OFF.		
Test the operation of motors (i.e. Direction of rotation)	Clockwise		
Check the functioning of VFD.	Working As Per Requirement		
Perform the SOP of operation.	Operate as per SOP		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.2 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 with no problems or adverse conditions.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

……

……

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.

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
ID.	:	Identification
No.	:	Number
OQ	:	Operational Qualification
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization
QA	:	Quality Assurance
VFD	:	Variable Frequency Drive
IQ	:	Installation Qualification

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)			