PERFORMANCE QUALIFICATION PROTOCOL FOR INLINE HOMOGENIZER–12.5 HP

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR INLINE HOMOGENIZER	PROTOCOL No.:

PROTOCOL CONTENTS

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR INLINE HOMOGENIZER	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			
HEAD (QUALITY CONTROL)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To carry out the Performance Qualification of Inline Homogenizer for manufacturing of liquid Preparation.
- To Provide Documented Verification that the Equipment as connected with ancillary system is suitable for indented purpose and produced product as per pre defined Acceptance Criteria.

3.0 SCOPE:

- The scope of this Performance Qualification is limited to qualification of Inline Homogenizer Installed in Oral Liquid Line.

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 of Performance Qualification Protocol. • To co-ordination with Production and Engineering to carryout Performance Qualification Activity.
Production	• Review of Performance Qualification Protocol. • To execution of Performance Qualification study as per Protocol.
Quality Control	• Review & Pre Approval of Performance Qualification Protocol. • Analytical Support (Microbiological Testing / Chemical Analysis)
Engineering	• Review of Performance Qualification Protocol. • To co-ordinate and execution support Performance Qualification Activity.

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 (INBETWEEN 0.5 TO 0.6mm) generates a shearing action which ensures the materials being processed are subjected to thousands of shearing actions each minute.

7.0 REASON FOR QUALIFICATION:

New equipment installed in Oral Liquid Line.

8.0 SITE OF STUDY:

Oral Liquid Line.

9.0 FREQUENCY OF QUALIFICATION

- After any major breakdown or after major modification
- Relocation of Equipments.

10.0 PRE – QUALIFICATION REQUIREMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the Performance Qualification report.

10.1 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Completed Yes/No	Checked By Engineering Sign/Date	Verified By QA Sign/Date
1.	Executed and approved Operational Qualification protocol cum report.			
2.	PQ Protocol approved.			
3.	SOP for Operation & Cleaning of Inline Homogenizer			
4.	SOP for Preventive Maintenance of Inline Homogenizer			

10.2 Training Record of Validation Team:

- All the persons involved in the execution of Performance Qualification activity must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working.
- Verify the training records and record the details in table mentioned in Performance Qualification report.

11.0 TESTS & CHECKS:

11.1 Verification Of Mixing Efficiency:

11.1.1 Objective:

- The purpose of this test is to ensure that Equipment Operates trouble free to prepare solution and solution prepared is homogeneous (without Lumps & clear solution) as seen visually and active contents are uniform.

11.1.2 Equipment / Instruments Used:

- Sugar & Purified water in sufficient quantity to make 250 Liter. Solution of Sugar.
- Sample collection using calibrated sampling rod.
- Sample containers or sample bags.

11.1.3 Method Applied:

- Switch on the Main Panel and start the Equipment as per respective SOP.
- On the Supply valve of Steam for Jacket through the Valve and Maintain the Temperature up to 70-90°C. and Steam Pressure 1.0 to 1.5 kg/cm^2
- Add the Ingredients as per defined in batch Manufacturing Record.
- Take the Samples after 15, 30 & 45 minute time interval of proper mixing of cycle. Sample to be

taken at identified potential areas of poor mixing. Sample to be taken at top and bottom. At Min and Maximum speed.

- Three consecutive trials must be tested as described before, in order to demonstrate Consistent performance.

11.1.4 Acceptance Criteria:

- At the 15, 30 & 45 minutes, take the sample & observe visually .The sample shall be free from lumps and visually should be Clear Liquid

11.1.5 Result Recording:

- Record the results of in Performance Qualification Report record the details of the instruments used including its Calibration Status.

12.0 CHECKLIST OF ALL TESTS & CHECKS

S.No.	Name of Test or Check	Execution (Yes/No)	Remark
1.	Verification of Mixing Efficiency		

13.0 REFERENCES:

- 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.
- SOP for "Operation & Cleaning of Sugar melting Tank".

14.0 DOCUMENTS TO BE ATTACHED:

- Any other Relevant Documents.
- Calibration Certificate of test Instruments.

15.0 NON COMPLIANCE:

In case of any Non-compliance observed during performance requalification, same shall be handled through SOP for Handling of Non-Compliance.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY

In case of any deviation observed during performance requalification, same shall be handled through SOP for Handling of Deviation.

17.0 CHANGE CONTROL, IF ANY

If any change is required during performance requalification, same shall be handled through SOP for Change Management.

18.0 ABBREVIATIONS:

%	:	Percentage
cGMP	:	Current Good Manufacturing Practices
RSD	:	Relatives Standard Deviation
LTD.	:	Limited
MFT	:	Sugar melting Tank
Nacl	:	Sodium chloride
No.	:	Number
OQ	:	Operational Qualification
PPQ	:	Performance Qualification Protocol
PVT	:	Private
QC	:	Quality Control
S.S	:	Stainless Steel
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization