PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR HOMOGENIZER	PROTOCOL No.:

1.0 REPORT APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved .The protocol cannot be used for execution unless approved by the following authorities.

This performance qualification protocol of Inline Homogenizer has been reviewed and approved by the following persons:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			QUALITY CONTROL		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To establish, check and document the performance of equipment in the established/predetermined operating ranges.

2.2 PURPOSE:

The purpose of this protocol is to verify that the equipment produces the desired output. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

The equipment working capacity is recommended by manufacturer challenged by charging the tablets with the maximum and minimum capacity of the pan.

2.3 SCOPE:

The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment shall meet the predetermined acceptance criteria.

The Scope of this protocol is limited to the performance qualification of Inline Homogenizer of manufacturing facility at ……..

Once the performance qualification of Inline Homogenizer has been completed successfully, the equipment shall be released for the production purposes.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Quality control , Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the performance qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The analysis of sample shall be carried out by quality control department.
- Engineering department shall support for execution.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Quality control / Production / Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory operation of the Inline Homogenizer shall be verified by executing the performance qualification studies described in this protocol. The successfully executed protocol documents that the Inline Homogenizer is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Inline Homogenizer. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 PREREQUISITE

3.1 Approved Standard operating procedure of the equipment shall be available.

3.2 The maximum and minimum capacity of the equipment shall be verified by taking the batch/lot to suit the requirement.

3.3 The installation and operational qualification of the equipment shall be successfully completed before the execution of the performance qualification.

3.4 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.

3.5 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

4.0 REVALIDATION CRITERIA:

The machine shall be re-validated if

- There are any major changes, which affect the performance of the equipment.
- After major breakdown maintenance is carried out.
- As per re-validation date and schedule

5.0 PERFORMANCE QUALIFICATION PROCEDURE:

5.1 BRIEF DESCRIPTION OF EQUIPMENT

Homogenizers are the device to form homogeneous solutions or dispersion 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 Model **OL-20HP** is powered by a 20HP motor. Where, due to high viscosity, vertical head or length of pipeline, the output falls below the required figure, it may be supplemented by the insertion of an auxiliary pump into the system without reducing the homogenizing efficiency of the machine.

The versatility built into this rugged machine provides 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 generates a shearing action which insures the materials being processed are subjected to thousands of shearing actions each minute.

The positive shearing action results in short process cycles and a more uniform, high quality product. Several interchangeable stator heads are available to maximize the desired results.

Installations cover a broad range of applications including emulsification, disintegration, dissolution, dispersion, and homogenization.

Unequalled versatility and the concept of positive mixing are combined to improve your operating efficiency. The key to achieve the best efficiency with this design is to maintain a maximum circulation of all materials through the rotor / stator at all times, during the process cycle. As viscosity increases, flow through the head decreases, thus lessening the work on a given volume of material while it is being circulated within the vessel. The in-line mixer emulsifier is less susceptible to this problem as it may be fed by means of positive displacement pumps.

In the Emulsifier, the work head is set into a wall, which divides the machine into two separate chambers, one with the inlet tube attached and the other with the outlet. Because of this construction it is physically impossible for any materials - liquid or solid - to pass from the inlet to the outlet without being subjected to the hydraulic and mechanical shear actions. By-passing is impossible.

The stators are available in different sizes and shapes. This makes it possible to adapt any machine to a variety of different processing operations including blending, mixing, emulsifying, homogenizing, disintegrating solids and suspending.

The major components of the homogenizer are:

- Rotor
- Stator
- Mechanical seal
- Operating Panel

5.2 Risk Analysis:

- The Inline Homogenizer is used for Homogenizing, Emulsifying, Dispersing, Mixing purpose of medicament liquid.
- During the process the temperature of the hopper is maintained to facilitate the Homogenizing, Mixing and keep medicament in molten stage.

S.No.	Risk identified	Control measures
1.	Temperature of the product	Product is thermolabile and manufactured at room temperature.
2.	Temperature of the jacket	Product is thermolabile and manufactured at room temperature so there is need to control of jacket temperature

EVALUATION & CONCLUSION

All the risks associated with Inline Homogenizer have been evaluated and control/preventive measures have been taken.

5.3 Methodology:

Methodology of the Inline Homogenizer is as follows:

- Inline Homogenizer is used to Homogenizing Mixing purpose of medicament liquid.
- The PQ of the Inline Homogenizer shall be done on PQ Batch manufactured under BMR No. _____ .

5.4 PRODUCT PROFILE:

Product details of the batches shall be verified from the BPR of the product and record in the following section:

Product Detail:

Product details shall be verified from the BMR of the product and record in the following table:

S.No.	Name of Product	Batch No.	Batch Size

Inference:

_____

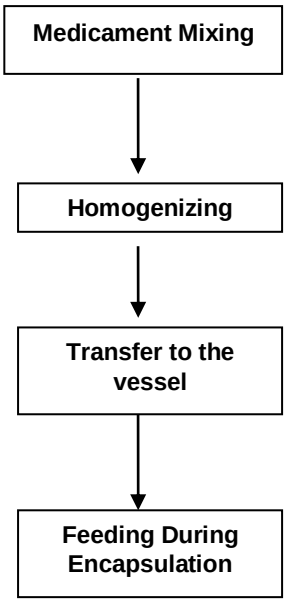
_____

_____

Reviewed By
Sign & Date

5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF INLINE HOMOGENIZER:

Process flow diagram of Inline Homogenizer is mentioned below:



5.6 SAMPLING MATRIX:

No sampling is required in the Performance Qualification of the Inline Homogenizer.

5.7 VERIFICATION OF PERFORMANCE QUALIFICATION:

Test Parameter	Specified Function	Observations	Verified By (Sign. & Date)
Physical Appearance of Medicament	Medicament shall be free from lumps, homogenized and free from gritty particles		
Operation of equipment	Inline Homogenizer shall be run smoothly during the whole process.		
Process Time	15 – 20 min.	From : _____ To : _____ Total Time : _____	
Temperature of Medicament	NMT 25°C		

Inference:

_____

_____

_____

Reviewed By
Sign & Date

5.8 ACCEPTANCE CRITERIA:

The test will be considered failed if the actual test results do not correspond to the expected results as following:

- Medicament shall be free from lumps, homogenized and free from gritty particles.
- Inline Homogenizer shall be run smoothly throughout the process.

6.0 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

7.0 PERFORMANCE QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION:

Prepared By
Sign/ Date

Checked By
Sign/Date

7.3 FINAL REPORT APPROVAL

The final report shall be signed after verifying that all the tests required in the qualification report of Inline Homogenizer are completed, reconciled and attached to the Qualification report or included in the qualification summary report and also verified that all amendments and discrepancies are documented, approved and attached to respective report. (If applicable) Signature in the block below indicates that all items in the qualification report of Inline Homogenizer have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

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REVIEWED BY			QUALITY ASSURANCE		
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			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		