PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR MEDICAMENT MIXING UNIT	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 Medicament Mixing Unit 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 Medicament Mixing Unit of manufacturing facility at ……..

Once the performance qualification of Medicament Mixing Unit 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 Medicament Mixing Unit (650 Liters) shall be verified by executing the performance qualification studies described in this report of the Medicament Mixing Unit (650 Liters). The successfully execution of the instructions mentioned in the report of the Medicament Mixing Unit (650 Liters) documents that the Medicament Mixing Unit (650 Liters) is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Medicament Mixing Unit (650 Liters).

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

The Medicament Mixing Unit (650 Liters) consists of following components:

1. **Medicament Mixer (with hydraulic lifting system)**
2. **Medicament Holding Vessel**
3. **Control Panel**

- Medicament mixer having lifting device for cleaning purpose.
- Power pack assembly with SS304 tank, oil filter, solenoid valve, DCV, FCV, pressure gauge, level indicator.
- 1 HP electrical motor direct connected to hydraulic pump.
- Hydraulic cylinder having lifting capacity 2500 kg.

- Unit duly supported on 4 Nos. SS pipes with 4 Nos. castor wheels of 4" diameter.

Note:

1. All rotating part will be covered with guard.
2. No sharp edges, easy to clean.
3. All glasses will be toughed glass.
4. Control panel should be wall mounted with speed control device.
5. Medicament Holding Vessel has different Equipment ID No.; performance qualification to be done with Medicament Mixing Unit.

5.2 Risk Analysis:

- Machine is designed to operate on high speed & negative pressure.
- A safety valve is installed on the jacket to avoid any damage due to high pressure.
- A speed reducer is installed to avoid the overheating of motor.
- A over load rely is installed to avoid any damage due to the over load.

S.No.	Risk identified	Control measures
1.	Damage due to high pressure.	A pressure gauge and safety valve is installed on the jacket to avoid any damage due to high pressure.
2.	Over heating of motor	A speed reducer is installed to avoid the overheating of motor.
3	Over loading on the motor	A over load rely is installed to avoid any damage due to the over load.
4	Temperature of the jacket and vessel	Separate temperature sensors for jacket and vessel to control the temperature.

EVALUATION & CONCLUSION

All the risks associated with Medicament Mixing Unit have been evaluated and control/preventive measures have been taken.

5.3 METHODOLOGY:

Read all notes for each steps before beginning the test steps. Verify and record verification of all critical operational functions. Challenge each of the control system and each sub system. Any function, system or subsystem that fails a particular challenge should be identified and corrected before proceeding to the next section of the testing criteria. Any modification to the equipment to enable compliance with the operation, process or Qualification Protocol must be documented and approved prior to completion of the challenged section. Any modification that has an effect to the

operation of the equipment must be challenged. Each challenge will be generated and approved by each department.

In the Medicament Manufacturing Vessel the medicament are mixed with taking required quantity of Raw material (Active + Excipients) with specified RPM and temperature for a specified time period.

Medicament Holding Vessels are used for intermediate storage of the prepared medicament.

- PQ batches of minimum and maximum batch sizes shall be manufacture to evaluate the performance of the Medicament Mixing Unit (650 Liters).
- The Medicament shall be manufactured as per BMR No. _____ & BMR No. _____ for minimum and maximum batch sizes respectively.
- Batch No. of minimum and maximum batch sizes shall be **300 kg & 650** kg__ respectively.
- Details of the PQ batches shall be mentioned under the heading of "**Product Details**".
- Start the Medicament preparation as per the BMR.
- Samples shall be sent to the QC Department for analysis.

5.4 PRODUCT PROFILE:

Product details of minimum and maximum batch size shall be verified from the BMR of the product and record in the following section:

5.4.1 Product Detail of Minimum Batch Size:

Product Name : _____

Product Code : _____

Batch Number : _____

Batch Size : _____

Mfg. Date : _____

Exp. Date : _____

BMR Number : _____

5.4.2 Product Detail of Maximum Batch Size:

Product Name : _____

Product Code : _____

Batch Number : _____

Batch Size : _____

Mfg. Date : _____

Exp. Date : _____

BMR Number : _____

Inference:

_____

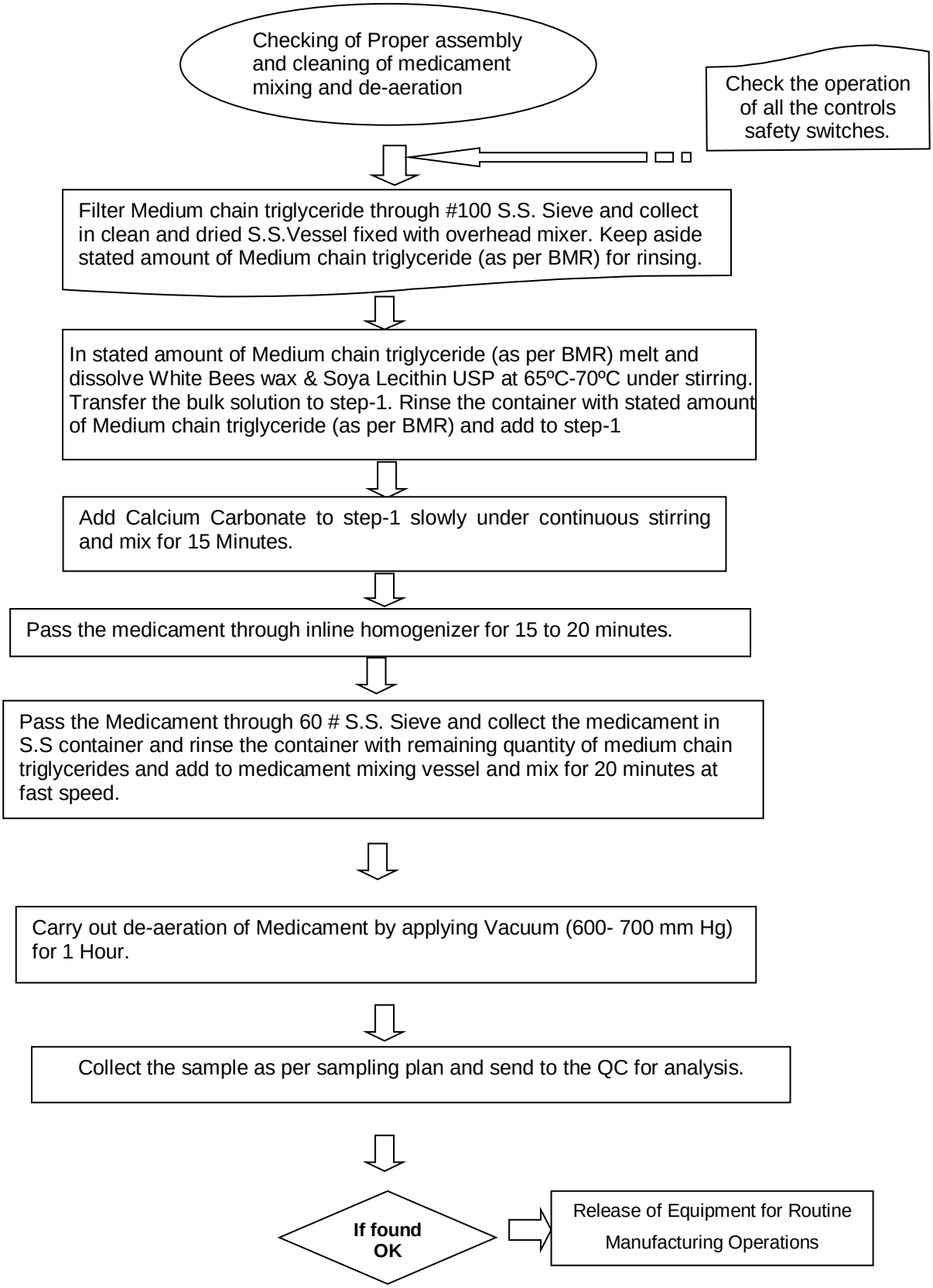
_____

_____

Reviewed By
Sign & Date

5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF MEDICAMENT MIXING UNIT:

Process flow diagram of Medicament Mixing Unit (650 Liters) is mentioned below:



5.6 SAMPLING MATRIX:

The Sampling Plan shall be as following:

S.No.	Sampling Position	Sampling Quantity	Test Required
1	Top	50 gm	Physical Appearance, Assay, Weight per ml. viscosity.
2	Middle	50 gm	Physical Appearance, Assay, Weight per ml. viscosity.
3	Bottom	50 gm	Physical Appearance, Assay, Weight per ml, viscosity.
4	Composite Sample from Top, Middle & Bottom	3 X 50 gm	Physical Appearance, Assay, Weight per ml. viscosity.

5.7 IN PROCESS PARAMETERS:

S.No.	Parameters	Limits
Medicament Preparation		
1.	Agitator Speed	25 to 35 RPM
Medicament Preparation		
2	Agitator Speed	10-15 RPM
3	Vacuum Pressure	600 to 700 mmHg
4	Air content	Free from Air Bubble
5	Consistency	Homogeneous Mixture
6	Viscosity	1000-25000 CPS

5.8 ACCEPTANCE CRITERIA:

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

- Assay should be achieved Not Less than 97% of the total RM used (Label claim + Overages)
- Uniformity of content.
- Viscosity in Brookfield viscometer should be in between 1000-25000 cps.
- Mixture should be homogeneous (free from lumps) and free flowing.

5.9 RECORDING OF SAMPLING:

Draw the samples as per Sampling Plan and send to QC for analysis. Record the details in the following table:

Batch No.: _____ **Date: / /**

Date	Time	Sampling Details	Quantity	Sampled By (Sign. & Date)

Batch No.: _____ **Date: / /**

Date	Time	Sampling Details	Quantity	Sampled By (Sign. & Date)

5.10 OBSERVATIONS AND RESULTS OF CHALLENGE TESTS:

OBSERVATIONS & RESULTS OF MINIMUM BATCH SIZE:

Batch No.: _____ **Date: / /**

S.No.	TEST PERFORMED	OBSERVATION				Compiled By Sign. & Date
		Top	Middle	Bottom	Composite	
1	Physical Checks of medicament					
2	Assay					
3	Weight per ml					
4.	viscosity					

OBSERVATIONS & RESULTS OF MAXIMUM BATCH SIZE:

Batch No.: _____ **Date: / /**

S.No.	TEST PERFORMED	OBSERVATION				Compiled By Sign. & Date
		Top	Middle	Bottom	Composite	
1	Physical Checks of medicament					
2	Assay					
3	Weight per ml					
4.	viscosity					

Inference:

_____

_____

_____

Reviewed By
Sign & Date

5.11 IN PROCESS CHECKS DURING MEDICAMENT PREPARATION & DE-AREATION:

S.No.	Time	Batch No.	Agitator RPM	Checked By

Inference:

_____

_____

_____

Reviewed By
Sign & Date

5.12 ENVIRONMENTAL MONITORING DURING MEDICAMENT PREPARATION:

Limit: Temperature (°C) : _____ ± ___°C Relative Humidity (%) : _____ ± ___

Date	Time	Batch No.	Temperature (°C)	RH (%)	Done By (Sing. & Date)

Inference:

_____

_____

_____

Reviewed By
Sign & Date

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 by the validation team after verifying that all the tests required in the qualification report of Medicament Mixing Unit (650 Liters) are completed, reconciled and attached to the report or included in the qualification summary report and also verified that all amendments and discrepancies are documented, approved and attached to respective repot (If applicable).

Signature in the block below indicate that all items in the qualification report of Medicament Mixing Unit (650 Liters) have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

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