1.0 PROTOCOL 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.

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

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of the operational qualification is to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document are the same at utmost transparency.

2.2 PURPOSE:

The purpose of this protocol is to establish the documentary evidence to ensure that the installed Medicament Mixing Unit shall operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specification.

2.3 SCOPE:

This protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the Medicament Mixing Unit operates and performs as intended in accordance with the design qualification.

The Scope of this protocol is limited to the operational Qualification of Medicament Mixing Unit installed in Feeding Room.

2.4 RESPONSIBILITY:

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

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

- Prepares the 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 operational checks, calibration of component, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons.

- Microbiologist shall expose the plate in bin washing machine.
- The production operator/supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering/Quality control :

- 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 shall be verified by executing the qualification studies described in this protocol .The successfully executed protocol documents that the Medicament Mixing Unit is operational and is satisfactorily working.

Execution team is responsible for the execution of operation of Medicament Mixing Unit. All executors involved with this protocol shall sign within the prescribed format given below.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The equipment shall be operational as per its specified operating instructions

3.2 All SOP's for the equipment to be verified and checked

3.3 Training shall be given to all the concerned personnel

3.4 All the functionality of equipment components to be checked.

3.5 All the safety feature and utility to be verified and checked

3.6 All calibrated component to be verified and checked.

4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule

5.0 OPERATIONAL QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

1	Equipment Name	:	Medicament Mixing Unit
2	Supplier/Manufacturer	:	Bectochem Consultants & & Engineers Pvt. Ltd.
3	Model	:	NA
4	Serial no.	:	NA
5	Location	:	Medicament preparation room

The Medicament Mixing Vessel (650 Liters) consists of Following Components:

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

- Medicament mixer having lifting device for cleaning purpose.
- Power pack assembly with SS304 tank, oil filter, solenoid valve, DCV, FCV, RLF, pressure gauge, level indicator.
- 10 HP electrical motor direct connected to hydraulic pump.
- Hydraulic cylinder having lifting capacity 2500 kg.
- Unit duly supported on 3 Nos. SS pipes with 3 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.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST

5.2.1 Write down the actual observation in observation column as per design specification

5.2.2 Observation functional parameter should be write actual function in specified column.

5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.

5.2.4 Whichever column is blank or not used ‘NA’ shall be used.

5.3 TEST INSTRUMENT DETAILS

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation of the Medicament Mixing Unit.

S.No.	Name Of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

Checked by Date:

Remark: ----------

Reviewed by (Sign/Date)

5.4 Verification of Calibrated component :

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard, which is to be used for the verification of the operation of the Medicament Mixing Unit.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration Due on	Certificate number

Checked by Date:

Remark: ----------

Reviewed by (Sign/Date)

5.5 VERIFICATION OF FUCTIONAL CHECKS:

OBJECTIVE: To verify the working efficiency and functional checks of the Medicament Mixing Unit (650 Liters).

PROCEDURE:

TEST RUN: Record the observation of operation qualification in the following checklist:

Name of System Component	Specified Function / Acceptance Criteria	Method of Verification	Observation	Verified By Sign/Date
Working Capacity	Should be 500 liters	By Challenging		
Feeding point	To feed the Medicament into the cooker	Visually		
Light Glass	To see inside the vessel during Processing	Visually		
Vacuum Connection	For creating the Vacuum into the vessel	Visually		
Hose Connection	For suction of Liquid Medicament Material	Visually		
Air Vent	For Air Release	Visually		
Material Out Let	For Prepared Medicament Discharge	Visually		
Temperature Indicator	Set the Temperature of the Vessel at 80° C	Visually		
Vacuum Pressure Gauge	Vacuum Pressure should be up to 760 mm Hg	Visually		
Water inlet	For Entering the water in the tank	Visually		

Name of System Component	Specified Function / Acceptance Criteria	Method of Verification	Observation	Verified By Sign/Date
Stirrer speed	Shall be measured by tachometer against set rpm 1. 10 rpm 2. 20 rpm 3. Max. rpm (Full Knob)	By Test Equipment	Observed RPM: 1. _____RPM 2. _____RPM 3. _____RPM	

PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR MEDICAMENT MIXING UNIT	PROTOCOL No.:

VERIFICATION OF FUCTIONAL CHECKS OF INLINE HOMOGENIZER:

Name of System Component	Specified Function / Acceptance Criteria	Method of Verification	Observation	Verified By (Sign & Date)
Main Power Supply	There should be no power supply to the machine when M.C.B. is off and vice versa.	By Challenging		
Direction of rotation of motor	The rotation should be in the clockwise direction	By Challenging		
Machine Operation	The running should be smooth and without vibration	Visually		
Polarity Test				
Interchange the wire from 'R' phase to 'B' phase.	The equipment should trip.	By Challenging		
Interchange the wire from 'B' phase to 'Y' phase.		By Challenging		
Interchange the wire from 'R' phase to 'Y' phase.		By Challenging		
Phase failure				
Remove the wire from 'R' phase; rest of the terminal shall remain intact.	The equipment should trip.	By Challenging		
Remove the wire from 'Y' phase; rest of the terminal shall remain intact.		By Challenging		
Remove the wire from 'B' phase; rest of the terminal shall remain intact.		By Challenging		

Remark: ----------

Reviewed by (Sign/Date)

5.6 VERIFICATION OF KEY FUCTIONAL OF MAJOR COMPONENT OF THE SYSTEM: Following component of the system have been verified for key functionality:

Control ON/OFF:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By twisting the knob towards **ON** position	Electricity supply should be start to the panel and **R, Y & B** Phase indicator shall glow.		
By twisting the knob towards **OFF** position	Electricity supply should be stop to the panel and **R, Y & B** Phase indicator shall **OFF**.		

Sight Lamp ON/OFF:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
By pressing the switch towards **ON** position	Lamp should be start		
By pressing the switch towards **OFF** position	Lamp should be stop		

Emergency Stop:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Push **Red** button.	Machine shall stop immediately.		

Knob for Agitator:

Method of Verification	Acceptance Criteria	Observation	Verified By Sign/Date
Rotate the Knob anticlockwise to reduce the speed & clockwise to	Speed of agitator shall be decrease & increase by rotating the knob		

increase the speed.	anticlock-wise and clockwise respectively.		

Inline Homogenizer:

Method of Verification	Acceptance Criteria	Observation	Verified By (Sign & Date)
Main switch **ON**	To supply the power to machine.		
Press Green Button	Inline Homogenizer should be start		
Press Red Button	Inline Homogenizer should be stop		

Lobe pump

Method of Verification	Acceptance Criteria	Observation	Verified By (Sign & Date)
Main switch **ON**	To supply the power to machine.		
Press Green Button	Lobe pump should be start		
Press Red Button	Lobe pump should be stop		
Rotate the Knob anticlockwise to reduce the speed & clockwise to increase the speed.	Speed of lobe pump shall be decrease & increase by rotating the knob anticlock-wise and clockwise respectively.		

Remark: ----------

Reviewed by (Sign/Date)

5.7 VERIFICATION OF SAFETY FEATURES:

Verify the operation of safety features and their functionality and record the observation in the following table of the respective report:

Safety Features Description	Function	Method Of Verification	Observation	Verified By Sign & Date
Earthing of motor	To avoid the accident due to the leakage of current.	Visually		
Safety valve	To avoid the accident due to high pressure in the jacket & Vessel.	Visually		
Safety features for Inline Homogenizer				
Over Load Rely	To avoid the damage of starter due to over load.	By challenging		
Oil seal and "O" rings	To prevent the leakage of the liquid from mill and oil from main motor. If any seal will damage; the liquid at the particular portion will leak, so by replacing that seal we can avoid further damage.	Visually		

Remark: ----------

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were verified as important for effective operation of the Medicament Mixing Unit.

S.No.	SOP title	SOP number	Verified by (Date sign)

Remark: ----------

Reviewed by (Sign/Date)

5.9 VERIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign & Date
1.	**Electricity:** 415 V AC , 3 Phase , 50 Hz	Physically with clamp meter		
2.	Chilled Water	Visually		
3.	Nitrogen	Visually		
4.	Vacuum	Visually		

Remark: ----------

Reviewed by (Sign/Date)

5.10 TRAINING RECORD OF PERSONNEL (S):

Following person has been trained during operation qualification about machine operation and setting parameter.

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

Remark: ----------

Reviewed by (Sign/Date)

5.11 Annexure (S)

Annexure No.	Details of Annexure

Remarks (if any)**:** ----------

Done By & Date: **Verified By & Date:**

5.12 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)

5.13 Abbreviation

Following Abbreviations are used in the Operational qualification protocol of Medicament Mixing Unit.

MOC : Material of Construction

RPM : Rotations per Minute

OQ : Operational Qualification

Sr. : Serial

SOP : Standard Operating Procedure

No. : Number

6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign / Date

Checked By
Sign / Date

6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol. (If applicable) signature in the block below indicates that all items in this qualification report of Medicament Mixing Unit have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After the successful operational qualification of the Medicament Mixing Unit the equipment can be taken for performance qualification.

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