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

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.

This Installation 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		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Medicament Mixing Unit and define the installation qualification requirements and acceptance criteria for the Storage Tank. Successful completion of these installation qualification requirements will provide assurance that the Medicament Mixing Vessel was installed as required in the manufacturing area.

The Qualification of Medicament Mixing Unit performed in view of Soft gel medicament preparation area of manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Medicament Mixing Unit received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

This Protocol is applicable to installation of Medicament Mixing Unit in soft gel medicament preparation area of the manufacturing facility.

2.4 RESPONSIBILITY:

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

Execution Team (Comprising members from Production, Engineering 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 installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
    - The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – 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 installation of the Medicament Mixing Vessel shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Medicament Mixing Unit is installed satisfactorily.

Execution team is responsible for the execution of installation of Medicament Mixing Unit.

Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The Medicament Mixing Unit shall meet the system description given in design qualification.

3.2 The Medicament Mixing Unit shall meet with the acceptance criteria mentioned under the topic “Identification of major components”

3.3 All material of constructions of the contact parts to be checked as per the specifications.

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 INSTALLATION QUALIFICATION PROCEDURE:

5.1 SYSTEM 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 In case of identification of major component actual observation should be written in specified location.

5.2.2 In case of the compliance of the test actual observation should be written in specified location.

5.2.3 For identification of utilities actual observation should be written in specified location.

5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.

5.2.5 Actual observation of the component should be written in specified location.

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

5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method Of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number	Visually/ Documental		
2	Verify that the "As Built" drawing is complete and represents the design concept.	Visually/ Physically		
3	Verify that there is no observable physical damage	Physically		
4	Examine All access ports are cleared of any debris.	Physically		
5	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
6	Verify that all electrical connections are properly done and safe	Physically		
7	Verify that the equipment is properly earthed	Physically		
8	Verify that utility line is properly connected	Physically		
9	Verify the proper leveling of equipment	Physically		
10	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		

S.No.	Statement	Method Of Verification	Actual Observation	Checked By Sign/Date
11	Equipment/system identification no. Is visible	Physically		
12	Any sharp or rough edges	Visually		

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

Reviewed by (Sign/Date)

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
MIXING UNIT					
Motor	Make	Bharat Bijlee	Physically		
	Spec.	10 HP, 1450 RPM, NON FLP	Physically		
	Sr. No.	To be recorded	Physically		
Gear Box	Make	NORD	Physically		
	Spec.	SK 9042.1 AF IEC 132 Ratio- 40.54	Physically		
Lobe Pump Motor	Make	BELKO	Physically		
	Spec.	2 HP, 1440 RPM	Physically		
	Sr. No.	To be recorded	Physically		
VFD for Motor	Make	ABB	Physically		
	Model	To be recorded	Physically/ Technical Specification		
	Spec.	7.5 – 5.5 KW	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically/ Technical Specification		
VFD for Lobe Pump Motor	Make	ABB	Physically		
	Model	To be recorded	Physically/ Technical Specification		
	Spec.	1.5-1.1 KW	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically/ Technical Specification		
Mechanical Seal	Make	Hi-Fab	Physically/ Technical Specification		

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
	Spec.	SSDB E1	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
Anchor Shaft	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø80	Physically/ Technical Specification		
Anchor Sweep	Make	BCEPL	Physically/ Technical Specification		
	Size	1500 X 10 Thk.	Physically/ Technical Specification		
Lifting Lug	Make	BCEPL	Physically/ Technical Specification		
	Size	20 Thk.	Physically/ Technical Specification		
Lift hydraulic system motor	Make	Bharat Bijlee	Physically		
	Model	MA09L45590L	Physically		
	Sr. No.	To be recorded	Physically		
Lift position sensor (upper and lower position)	Make	Inductive	Physically		
	Model	STIM18	Physically		
	Qty.	02	Physically		
Pressure gauge with safety valve & needle valve	Make	Baumer	Physically		
	Spec.	4” Dial, ½” BSP, 0-7 Kg/cm^2	Physically/ Technical Specification		
Temperature Sensor for Jacket	Make	Eureka	Physically/ Technical Specification		
	Model	PT-100	Physically/ Technical Specification		
Nozzles					

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
N1	Location	Hand hole	Physically		
	Size	6 Thk.	Physically/ Technical Specification		
N2	Location	Sight Glass	Physically		
	Size	Ø 100	Physically/ Technical Specification		
N3	Location	Material Inlet	Physically		
	Size	Ø 75 x 14 SWG	Physically/ Technical Specification		
N4	Location	Safety Valve	Physically		
	Size	Ø 38 x 14 SWG	Physically/ Technical Specification		
N5	Location	Water inlet	Physically		
	Size	Ø 38 x 14 SWG	Physically/ Technical Specification		
N6	Location	Spare	Physically		
	Size	Ø 38 x 14 SWG	Physically/ Technical Specification		
N7	Location	Spare	Physically		
	Size	Ø 38 x 14 SWG	Physically/ Technical Specification		
INLINE HOMOGENIZER (EQUIPMENT NO.:EQI/SGD/ILH/001)					
Motor	Make	Bharat Bijlee	Visually / Physically		
	Spec.	15/20 KW/ HP, 2920 RPM, 337-450 V	Visually / Physically		
	Sr. No.	To be recorded	Visually / Physically		
V Belt	Make	Neoprene	Physically		

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
	Spec.	A-49/1280LP	Physically		
	Qty.	5 Nos	Physically		
Castor wheel	Make	Swiss Engineers	Physically		
	Spec.	2''	Physically		
	Qty.	4 Nos	Physically		
MEDICAMENT HOLDING VESSEL (EQUIPMENT NO.: EQI/SGD/MHV/001)					
Medicament Holding Vessel	Make	BCEPL	Physically/ Technical Specification		
	Qty.	01 No.	Visually / Physically		
	Gross Capacity	650 ltrs.	Physically/ Technical Specification		
	Working Capacity	600 ltrs.	Physically/ Technical Specification		
Main Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Top Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Bottom Dish End (Bowl)	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Body Flange	Make	BCEPL	Physically/ Technical Specification		
	Size	25 mm	Physically/ Technical Specification		

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
Jacket Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk.	Physically/ Technical Specification		
Jacket Dish (Bowl)	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Insulation Shell/ Dish	Make	BCEPL	Physically/ Technical Specification		
	Size	2 Thk.	Physically/ Technical Specification		
Nozzles					
N1	Location	Thermowell	Physically		
	Size	1” NB X SCH 40	Physically/ Technical Specification		
N2	Location	Jacket Vent	Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		
N3	Location	Bottom Outlet	Physically		
	Size	Ø50	Physically/ Technical Specification		
N4	Location	Jacket Inlet	Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		
N5	Location	Jacket Outlet	Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		
N6	Location	Jacket Drain	Physically		

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
	Size	½" NB X SCH 40	Physically/ Technical Specification		
MEDICAMENT HOLDING VESSEL (EQUIPMENT NO.: EQI/SGD/MHV/002)					
Medicament Holding Vessel	Make	BCEPL	Physically/ Technical Specification		
	Qty.	01 No.	Visually / Physically		
	Gross Capacity	650 ltrs.	Physically/ Technical Specification		
	Working Capacity	600 ltrs.	Physically/ Technical Specification		
Main Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Top Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Bottom Dish End (Bowl)	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Body Flange	Make	BCEPL	Physically/ Technical Specification		
	Size	25 mm	Physically/ Technical Specification		
Jacket Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk.	Physically/ Technical Specification		

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
Jacket Dish (Bowl)	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Insulation Shell/ Dish	Make	BCEPL	Physically/ Technical Specification		
	Size	2 Thk.	Physically/ Technical Specification		
Nozzles					
N1	Location	Bottom Outlet	Physically		
	Size	Ø50	Physically/ Technical Specification		
N2	Location	Jacket Inlet	Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		
N3	Location	Jacket Outlet	Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		
N4	Location	Jacket Drain	Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		
N5	Location	Jacket Vent	Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		
N6	Location	Thermowell	Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		
MEDICAMENT HOLDING VESSEL (EQUIPMENT NO.: EQI/SGD/MHV/003)					

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
Medicament Holding Vessel	Make	BCEPL	Physically/ Technical Specification		
	Qty.	01 No.	Visually / Physically		
	Gross Capacity	650 ltrs.	Physically/ Technical Specification		
	Working Capacity	600 ltrs.	Physically/ Technical Specification		
Main Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Top Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Bottom Dish End (Bowl)	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Body Flange	Make	BCEPL	Physically/ Technical Specification		
	Size	25 mm	Physically/ Technical Specification		
Jacket Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk.	Physically/ Technical Specification		

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

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
Jacket Dish (Bowl)	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Insulation Shell/ Dish	Make	BCEPL	Physically/ Technical Specification		
	Size	2 Thk.	Physically/ Technical Specification		
Nozzles					
N1	Location	Bottom Outlet	Physically		
	Size	Ø50	Physically/ Technical Specification		
N2	Location	Jacket Inlet	Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		
N3	Location	Jacket Outlet	Physically		
	Size	25NB X SCH 40	Physically/ Technical Specification		
N4	Location	Jacket Drain	Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		
N5	Location	Jacket Vent	Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		
N6	Location	Thermowell	Physically		
	Size	½" NB X SCH 40	Physically/ Technical Specification		

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

Reviewed by (Sign/Date)

5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name of Components	Material of Construction	Method of Verification	Observation	Verified By Sign/Date
Main Shell	SS 316 L	By Molybdenum Kit/ Test Certificate		
Top Dish End	SS 316 L	By Molybdenum Kit/ Test Certificate		
Bottom Dish End (Bowl)	SS 316 L	By Molybdenum Kit/ Test Certificate		
Body Flange	SS 316	By Molybdenum Kit/ Test Certificate		
Jacket Shell	SS 304	By Molybdenum Kit/ Test Certificate		
Jacket Dish (Bowl)	SS 304	By Molybdenum Kit/ Test Certificate		
Insulation Shell/Dish	SS 304	By Molybdenum Kit/ Test Certificate		
Mechanical Seal	SS 316	By Molybdenum Kit/ Test Certificate		
Anchor Shaft	SS 316L	By Molybdenum Kit/ Test Certificate		
Anchor Sweep	SS 316L	By Molybdenum Kit/ Test Certificate		
Lifting Lug	SS 304	By Molybdenum Kit/ Test Certificate		

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

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign & Date
1	**Electricity:** 415 V/ 3 Ph/ 50 Hz	Physically with clamp meter		
2	Water	Visually		
3	Steam	Visually		
4	Vacuum	Visually		

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

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF SAFETY FEATURES:

Identify and record the safety/interlocking features (if any) and their function in following tables:

Safety Features Description	Function	Method of verification	Observation	Checked 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		

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

Reviewed by (Sign/Date)

5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

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

Reviewed by (Sign/Date)

5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

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

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S.No.	SOP Title	Verified By Sign/ Date

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

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	Drawing And Document Detail	Verified By Sign/Date

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

Reviewed by (Sign/Date)

5.11 ABBREVIATIONS

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

MOC : Material of construction

V : Volts

HZ : Hertz

mm : Millimeter

Spec. : Specification

Qty. : Quantity

ltrs. : Liters

BCEPL: Bectochem Consultants & Engineers Pvt. Ltd.

NA: Not applicable

Thk.: Thickness

GMP: Good manufacturing Practice

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 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any)**:**

_____

_____

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

6.0 INSTALLATION 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. 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 installation qualification of the Medicament Mixing Unit the equipment can be taken for operational qualification.

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