USER REQUIREMENT SPECIFICATION

FOR

MULTI MIX MANUFACTURING PLANT

(OINTMENT SECTION)

LOCATION	**OINTMENT SECTION**
SUPERSEDES URS No.	**NIL**

CONTENTS

1.0 APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- The User Requirements Specification (URS) is provided to aid the user through the critical aspects of Fabrication, Facility for Installation of Required Instruments, Cleaning / Proper Maintenance, cGMP, Safety and Regulatory Requirements necessary to construct and fabricate a functional Multi mix manufacturing Plant that meets the user's needs in the most cost-effective method possible.
- The URS is then provided to Vendor to submit a Price Quote for procurement of Multi mix manufacturing Plant.
- The URS shall help Vendor in understanding the end user requirement in details. This document shall help vendor for developing the Design Specification, which on approval will become a Contractual Agreement between Vendor and Site.
- This URS Shall be recognized as an integral part of the procurement agreement with the vendor. The vendor will abide by the information and conditions set forth by this document as well as the Standard Purchase Terms and Conditions.

3.0 SCOPE:

- The scope of this document is limited to the User Requirement Specification (URS) of Multi mix manufacturing.
- The URS shall be used as a reference document for Design Qualification considering all aspects of Current Good Manufacturing Practices (cGMP) and Safety.

4.0 RESPONSIBILITY:

The Team, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this URS.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation and Approval of User Requirement Specification. • Co-ordination with User Department to prepare User Requirement Specification. • To check the completeness and Technical Accuracy of the URS.
User Department	• Review of User Requirement Specification for compliance with the Product Requirement.
Engineering	• Review of User Requirement Specification. • Assist in preparation of User Requirement Specification.

5.0 GMP/REGULATORY REQUIREMENTS:

The Purpose of procuring Multi mix manufacturing Plant is to perform filling of bulk as well as sealing of tube crimp in Ointment section.

- Multi mix manufacturing Plant should comply with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.

6.0 SYSTEM OVERVIEW:

To design and manufacture multi mix plant for processing of ointment / cream / gels / lotion as per product safety, cGMP guideline and to provide assurance that the equipment is manufactured as per the URS and it complies with the scope of supply.

1. Multi mixer manufacturing vessel
2. Wax phase vessel
3. Transfer pump
4. Electric control panel
5. Vacuum pump
6. Utility system
7. Batch storage vessel working platform
8. Homogenizer
9. Meter in jump

6.1 TECHNICAL SPECIFICATION

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	SS 316	Multi mix manufacturing Plant
2.0	Modal /Type	…….	MP 500
3.0	manufacturing vessel	SS 316	750 ltr. Gross or 500 kg
4.0	CIP Connection	.....	As per cGMP requirement
5.0	Wax phase melting vessel	SS 316	420 ltr. Gross or 350 ltr.
6.0	Water phase melting vessel	SS 316	420 ltr. Gross or 350 ltr.
7.0	Batch Storage vessel	SS 316	750Ltrs or 500 kg
8.0	Working Platform	SS 304	Dimple Sheet
9.0	Transfer Pump	SS 304	As per cGMP Requirement
10.0	Inbuilt Homogenizer in mfg. tank	-----	As per cGMP Requirement
11.0	VFD for Homogenizer	-----	As per cGMP Requirement
12.0	Vacuum pump	-----	As per cGMP Requirement
13.0	Interconnecting Pipeline	-----	As per cGMP Requirement
14.0	Meter-in Pump	-----	As per cGMP Requirement

S.No.	Name of the Component	MOC	Technical Specification
15.0	Automated Utilities For Service of Plant	-----	As per cGMP Requirement
16.0	Automated PLC operation	-----	As per cGMP Requirement
17.0	Load Cells	-----	As per cGMP Requirement
18.0	scrapper	Food Grade	As per cGMP Requirement
19.0	FLP Motors	-----	As per cGMP Requirement

7.0 OTHER REQUIREMENTS AND CONSTRAINTS:

7.1 FUNCTIONAL REQUIREMENTS:

- Multi mix manufacturing Plant shall comply as per ISPE, cGMP, cGEP Guidelines.

7.2 RELIABILITY AND AVAILABILITY:

- The system shall be available for continuous operation.
- The electrical and other material of construction used shall be suitable for the intended service so as to withstand the working stress without frequent break down.

7.3 MAINTENANCE:

- The system shall allow for maintenance by trained site personnel with supplier recommended tools and practices.
- Recommended spare parts list shall be provided.
- The supplier shall replace the parts found to be damaged/ broken during installation.
- The supplier shall be available at the site when asked in case of major breakdown.

8.0 LIFE CYCLE:

8.1 DEVELOPMENT:

- The supplier shall follow cGMP in design, development, construction and Installation of the Machine.

8.2 TESTING:

- The system shall be Factory tested by the supplier with approval witness.
- The system shall be commissioned and qualified at site for Installation and Operation by the supplier with approval witness.

8.3 SUPPORT:

- Supplier shall provide support for Preventive maintenance plan development, Operation & cleaning procedure for Multi mix manufacturing Plant, Assembly and Operator training.
- Supplier shall provide Safety Manuals during Installation, Operation & Calibration at the site.

8.4 DELIVERY:

- All parts of the system shall be sourced, delivered and installed by the Supplier.
- The supplier shall provide Functional design specification (MOC & Calibration Certificates) and Operation Manual in Soft as well as Hard Copy.

9.0 DOCUMENTS TO BE PROVIDED:

- All MOC Certificates, Manual for Bought out items.
- Design Qualification protocol.
- Installation Qualification protocol.
- Operational Qualification protocol.
- Schematic Diagram of machine showing Overall Dimensions.
- Instrument list with manufacturer's calibration certificate.
- GA Drawing.
- Operating & Service Manual
- Spare Part List.
- Warranty Certificate of machine

Note: The whole URS is a tentative document. Manufacturer or Vendor will be solely responsible for performance of machine specified in the catalogue or during discussion at the time of finalization of purchase order. Specifications and details mentioned in the DQ, duly signed by Vendor/ Manufacturer and duly signed by Head QA will be treated as final specifications of the machine.

The said DQ will be treated as an integral part of purchase order.

10.0 REVIEW COMMENTS:

- For any changes in the design/make of the Multi mix manufacturing Plant if not as per the URS, prior intimation/approval should be taken by the supplier.
- All parts should have MOC certificates, test certificates, Calibration certificates for traceability and authenticity.

Approved By: _____
Head QA
Sign/Date