



**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING  
MACHINE GAN COMBI  
(OINTMENT SECTION)**

<b>LOCATION</b>	<b>OINTMENT SECTION</b>
<b>SUPERSEDES URS No.</b>	<b>NIL</b>



**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

**CONTENTS**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
<b>1.0</b>	<b>Approval</b>	<b>3</b>
<b>2.0</b>	<b>Objective</b>	<b>4</b>
<b>3.0</b>	<b>Scope</b>	<b>4</b>
<b>4.0</b>	<b>Responsibility</b>	<b>5</b>
<b>5.0</b>	<b>GMP / Regulatory Requirements</b>	<b>5</b>
<b>6.0</b>	<b>System Overview</b>	<b>6</b>
<b>6.1</b>	<b>Technical Specification</b>	<b>6</b>
<b>7.0</b>	<b>Other Requirement and Constraints</b>	<b>8</b>
<b>7.1</b>	<b>Functional Requirements</b>	<b>8</b>
<b>7.2</b>	<b>Reliability and Availability</b>	<b>8</b>
<b>8.0</b>	<b>Life Cycle</b>	<b>8</b>
<b>8.1</b>	<b>Development</b>	<b>8</b>
<b>8.2</b>	<b>Testing</b>	<b>8</b>
<b>8.3</b>	<b>Support</b>	<b>9</b>
<b>8.4</b>	<b>Delivery</b>	<b>9</b>
<b>9.0</b>	<b>Documents to be Provided</b>	<b>9</b>
<b>10.0</b>	<b>Review Comments</b>	<b>10</b>



**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

**1.0 APPROVAL:**

**INITIATED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (QUALITY ASSURANCE)</b>			



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

**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 Double Head Ointment filling and sealing machine 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 Double Head Tube Filling Machine GAN Combi.
- 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 of the site.

**3.0 SCOPE:**

- The scope of this document is limited to the User Requirement Specification (URS) of Double Head Tube Filling Machine GAN Combi of site.
- The URS shall be used as a reference document for Design Qualification considering all aspects of Current Good Manufacturing Practices (cGMP) and Safety.



**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

**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.

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Initiation and Approval of User Requirement Specification.</li><li>• Co-ordination with User Department to prepare User Requirement Specification.</li><li>• To check the completeness and Technical Accuracy of the URS.</li></ul>
<b>User Department</b>	<ul style="list-style-type: none"><li>• Review of User Requirement Specification for compliance with the Product Requirement.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review of User Requirement Specification.</li><li>• Assist in preparation of User Requirement Specification.</li></ul>

**5.0 GMP/REGULATORY REQUIREMENTS:**

The Purpose of procuring Double Head Tube Filling Machine GAN Combi is to perform filling of bulk as well as sealing of tube crimp in Ointment section.

- Double Head Ointment filling and sealing machine should comply with the “Current Good Manufacturing Practices”.
- Schedule–M “Good Laboratory Practices and Requirements of Premises, Plant & Equipments for Pharmaceuticals Products”.



**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

**6.0 SYSTEM OVERVIEW:**

Double Head Tube Filling Machine GAN Combi which consists of Cassette in feed, I mark Registration, cleaning, filling, Product Reservoir, sealing and Ejection system.

**6.1 TECHNICAL SPECIFICATION**

S.No.	Name of the Component	MOC	Technical Specification
1.0	Equipment Name	----	Double Head Double Head Tube Filling Machine GAN Combi
2.0	Modal /Type	----	GAN Combi
3.0	Type of Tube	----	Aluminum/Lami/Plastic
4.0	Speed	----	120 tubes/min.
5.0	Overall Size of the Machine	----	As per your specification
6.0	Top & bottom frame	SS 316 L	As per cGMP Requirement
7.0	No. of head filling	SS 316 L	2 Head
8.0	filling nozzle	SS 316 L	As per cGMP Requirement
9.0	Double Jacketed Hopper	SS 316 L	With cover fitted with electrical heater
			Temperature Controller with water supply
10.0	Stirrer	SS 316 L	With VFD
11.0	Panels	SS304	As per cGMP Requirement
12.0	Cassette Box	----	Fully automatic in feed Device
13.0	Photo Electric Registration device	----	For 'I' mark registration
14.0	VFD	----	As per cGMP Requirement
15.0	Central Lubrication System	----	Motorized
16.0	Tube Cleaning System	----	Ionized System
17.0	Level Sensor	----	For Hopper
18.0	Trim Collector	----	As per cGMP Requirement
19.0	Machine body	SS316L	All Contact Parts
		SS304	Non Contacts
20.0	Tube Ejector	SS304	As per cGMP Requirement
21.0	Overload Clutch	----	Self Centering



PHARMA DEVILS

**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

S.No.	Name of the Component	MOC	Technical Specification
22.0	Cladding	SS 304	As per cGMP Requirement
23.0	Motor	-----	1.5 HP , worm reduction gear box with sprockets
24.0	Pump for filling	-----	15mm (1-6cc) to 60mm (30-250cc) bulk transfer lobe pump.
25.0	Drive	-----	Ferguson Frequency Drive
26.0	Link up Programme	-----	With Autocartanator
27.0	PLC	-----	Allen Bradley 3 level Password
28.0	Emergency Switch	-----	Push Button
29.0	Safety Features	-----	<ul style="list-style-type: none"> <li>➤ Emergency push button shall be provided.</li> <li>➤ Machine shall not be started without safe earthing.</li> <li>➤ All moving parts to be protected with safety guards.</li> <li>➤ All upper guards provided with interlocks.</li> <li>➤ Noise pollution shall be kept below 85 db.</li> <li>➤ Alarm should be provided</li> </ul>
30.0	Limit Switch / Inter Locking System	-----	As per your specification
31.0	Indicating lamp	-----	As per your specification
32.0	Safety Guard	-----	As per your specification
33.0	Earthing	-----	Whole body Earthing
34.0	<b>Utilities</b>		
	<b>Electrical Configuration &amp; Cabling</b>		
	Power Supply	-----	As per your specification and Finalized Purchase order.
	Power cable	-----	
Power / Inverter	-----	Should be Provided as per your specification and Finalized Purchase order.	
35.0	Special feature	-----	As per Purchase order.



**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

**7.0 OTHER REQUIREMENTS AND CONSTRAINTS:**

- Complete Change Parts: 16 mm dia., 19 mm dia., 22 mm dia., 25 mm dia. With minimum range of tube length of 65 mm tubes.
- Filling accuracy i.e. wt variation should be  $\pm 1.0\%$ .
- One set of tools.
- Inkjet printing facility on tube inbuilt machine with online features.
- Lami tube sealer for sealing both Lami as well as Plastic tubes with or without seams.
- Gauges, flow meters, filters, interconnecting chilled water and compressed air piping.

**7.1 FUNCTIONAL REQUIREMENTS:**

- Double Head Ointment filling and sealing machine 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.





**USER REQUIREMENT SPECIFICATION  
FOR  
DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI**

**URS No.:**

- 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 Double Head Ointment filling and sealing machine, 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.
- G.A 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.**

 <b>PHARMA DEVILS</b>	<b>USER REQUIREMENT SPECIFICATION FOR DOUBLE HEAD TUBE FILLING MACHINE GAN COMBI</b>	<b>URS No.:</b>
--	--	-----------------

**10.0 REVIEW COMMENTS:**

- For any changes in the design/make of the Double Head Tube Filling Machine GAN Combi 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**