



Kerala State Homoeopathic Co-Operative Pharmacy Ltd.

(sponsored by government of Kerala & aided by govt. of India)
Office: Pathirappally, Alappuzha, Kerala, India. Pin-688 521

Phone : 477 2258012
:477 2258665

Website : www.homcokerala.com

Email : homcokerala@gmail.com

Supplier's Copy

USER REQUIREMENT SPECIFICATION

Name of the Company	:	
Contact Person	:	
Address	:	
Contact Details	:	
Department	:	<i>Ointment – (Ground Floor)</i>
Equipment and Code No.	:	<i>Ointment Manufacturing Plant (Steam heating)</i>
Name of work	:	Supply, Installation, Commissioning & Validation of cGMP model Ointment Manufacturing Plant – 100 KG at M/s. HOMCO –Kerala
Ref. No.	:	
Date	:	
Enclosures	:	
Quantity	:	1 No.



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OINTMENT MANUFACTURING PLANT – 100 Kgs (STEAM HEATED)

ANNEXURE - I : BASIC DETAILS OF THE MACHINE

DESCRIPTION (To be specified by the supplier, if any variation)	
Scope	: <ul style="list-style-type: none">Supply, Installation, Commissioning & Validation of cGMP model SS 316 Ointment Manufacturing Plant with all interconnecting piping, pumps, SS platform etc. and all the items which is required to run the plant along with connecting accessories, cables etc. at M/s. HOMCO –KeralaInvolvement of Third Party Inspection Agency (TPIA) in the Design, Verification of Materials, Fabrication, Inspection, Testing of vessels [Manufacturing Vessel, Wax Phase Vessel, Water Phase Vessel, Batch Storage Vessel]
Machine	: Ointment Manufacturing Plant (Steam heated plant)
Model	: *
Type	: *
Capacity (In litres)	: Working: 100 kgs * : : 120 to 125 liters * : Gross : 150 to 160 liters*
The Main plant Consist of	: <ol style="list-style-type: none">1) Manufacturing Vessel2) Wax Phase Vessel3) Water Phase Vessel4) Batch Storage Vessel5) Twin Lobe Pump (2 Nos)6) Transfer Pump7) Vacuum Pump and8) Interconnecting piping9) Working10)platform11) Control panel
➤ The vendor shall design the vessels based on the capacity mentioned. The design including calculation and drawings shall be appraised by the Pharma Consultant.	

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE – II, III and IV : cGMP FEATURES Process Control Operational features

DESCRIPTION	
(To be specified by the supplier, if any variation)	
1) Manufacturing Vessel	
Capacity	: Working : 120 to 125 liters (100 Kgs) : Gross : 150 to 160 liters *
MOC	: Contact parts : SS 316 Non-contact parts : SS 304
Specific gravity	: 0.9 gm/cc *
Shell	: 5.0 mm thick SS 316 cylindrical with flange
Bottom	: 5.0 mm thick SS 316 conical dish end welded with shell
Top	: 5 mm thick SS 316 Tori spherical dish end welded with flange
Flange	: 16 mm thick SS 316 -2 Nos. welded
Jacket	: 4 mm thick SS 304 with spiral stiffeners
Gasket	: Food Grade Silicon Gasket
Insulation	: 50 mm thick mineral wool duly cladded with 14 SWG SS 304 sheet
Legs	: 4 Nos. SS 304 pipe with base plate to suit load cell bracket
Load cell	: 4 Nos. 500kg, with junction box and FLP digital weight indicator and 0.05% accuracy least count 500 gms in total volume
❖ Hydraulic Lifting Arrangement to lift top Agitator Assembly with Lid	

* To be specified and confirm by the supplier as per their equipment design



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DESCRIPTION

(To be specified by the supplier, if any variation)

Vessel Connections :

Hand hole	:	150 mm dia with hinge type lid and silicon 'O' ring
Light glass	:	4" dia with flange
Sight glass	:	4" dia on hand hole Lid with wiper
Vacuum Inlet	:	1 1/2" dia TC end
CIP connection	:	2x1" dia TC 2 nos. with common header for spray ball
Pressure Transmitter	:	1 1/2" dia TC end
Extra nozzle	:	1" dia TC end -1 no.
Anchor Stirrer	:	On center of top dish
Product recirculation	:	1 1/2" dia TC end (On top of dish)
Product temperature	:	1 1/2" dia TC end
Product outlet	:	Through homogenizer by Tee connection
Homogenizer	:	In line, Rotor & Stator type, Skid mounted, 7.5 HP/2800 rpm for re-circulating the material back into the vessel and used to transfer product mounted at the bottom

Vessel Design parameters :

Working temperature	:	30 to 125 degree C.
Design Temperature	:	20 to 135 degree C.
Working pressure	:	-1 to 2 kgs/cm sq.
Design pressure	:	-1 to 2.25 kgs/cm sq.
Hydro test pressure	:	-1 to 3.0 kgs/cm sq.

*** To be specified and confirm by the supplier as per their equipment design**

DESCRIPTION

(To be specified by the supplier, if any variation)

Jacket Design parameters :



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Working temperature	:	35 to 135 degree C. *
Design Temperature	:	25 to 150 degree C. *
Working pressure	:	3.5 to 4 kgs/cm sq. *
Design pressure	:	4.0 to 4.5 kgs/cm sq. *
Hydro test pressure	:	5.5 to 6.0 kgs/cm sq. *
Jacket nozzles connections	:	For Steam inlet, cooling water outlet, pressure gauge etc. 1½"dia TC end
Miscellaneous details		
Agitator	:	Anchor type semi-contra designed with Teflon scrapper and self-adjusted
Stationary Baffles	:	2 stationary baffles for breaking mass movement and push the mass on center
Motor	:	3 HP /1440 rpm
Gear Box	:	30:1 ratio
Shaft seal	:	Dry mechanical seal with cooling arrangement
Accessories:		
VFD	:	Anchor Stirrer and Homogenizer
Compounding gauge	:	Diaphragm type
Pressure sensor	:	1 to 5.0 kgs/cm sq.
Spray ball	:	360 degree rotating type

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DESCRIPTION	
(To be specified by the supplier, if any variation)	
2) WAX Vessel	
Capacity	: Working : 50 to 60 liters (50 Kgs) : Gross : 75 to 85 liters
MOC	: Contact parts : SS 316 Non-contact parts : SS 304
Specific gravity	: 0.9 gm/cc *
Shell	: 4.0 mm thick SS 316 cylindrical with flange
Bottom	: 4.0 mm thick SS 316 conical dish end welded with shell
Top	: 4 mm thick SS 316 Tori spherical dish end welded with flange ,manual lid lifting with davit arm
Flange	: 18 mm thick SS 316 -2 Nos. welded
Jacket	: 4 mm thick SS 304 with spiral stiffeners
Gasket	: Food Grade Silicon Gasket
Insulation	: 50 mm thick mineral wool duly cladded with 14 SWG SS 304 sheet
Legs	: 4 Nos. SS 304 pipe with base plate to suit load cell bracket
Vessel Connections :	
Hand hole	: 150 mm dia with hinge type lid and silicon 'O' ring
Light glass	: 4" dia with flange
Sight glass	: 4" dia on hand hole Lid with wiper
Vacuum Inlet/VB/CG	: 1 ½" dia TC end
CIP connection	: 2"x1" dia TC end with common header for spray ball
Anchor Stirrer	: On center of the top dish

*** To be specified and confirm by the supplier as per their equipment design**



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DESCRIPTION	
(To be specified by the supplier, if any variation)	
Vessel Connections :	
Product temperature	: 1½" dia TC end
Product outlet	: Flush bottom valve
Vessel Design parameters :	
Working temperature	: 30 to 125 degree C.
Design Temperature	: 20 to 135 degree C.
Working pressure	: -1 to 2 kgs/cm sq.
Design pressure	: -1 to 2.25 kgs/cm sq.
Hydro test pressure	: -1 to 3.0 kgs/cm sq.
Jacket Design parameters :	
Working temperature	: 35 to 135 degree C. *
Design Temperature	: 25 to 150 degree C. *
Working pressure	: 3.5 to 4 kgs/cm sq. *
Design pressure	: 4.0 to 4.5 kgs/cm sq. *
Hydro test pressure	: 5.5 to 6.0 kgs/cm sq. *
Jacket nozzles connections	: For Steam inlet, cooling water outlet, pressure gauge etc. 1½" dia TC end

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DESCRIPTION

(To be specified by the supplier, if any variation)

Miscellaneous details

Agitator	:	Anchor type semi-contra designed with Teflon scrapper and self-adjusted
Motor	:	2 HP /1440 rpm
Gear Box	:	30:1 ratio
Shaft seal	:	Oil seal

Accessories:

VFD	:	Anchor Stirrer and Homogenizer
Compounding gauge	:	Diaphragm type
Temperature sensor	:	0 to 250 degree C with class A accuracy
Spray ball	:	360 degree rotating type

*** To be specified and confirm by the supplier as per their equipment design**



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DESCRIPTION	
(To be specified by the supplier, if any variation)	
3) Water Vessel	
Capacity	: Working : 120 to 125 liters (100 Kgs) : Gross : 150 to 160 liters *
MOC	: Contact parts : SS 316 Non-contact parts : SS 304
Specific gravity	: 0.9 gm/cc *
Shell	: 4.0 mm thick SS 316 cylindrical with flange
Bottom	: 4.0 mm thick SS 316 elliptical dish end welded with shell
Top	: 4 mm thick SS 316 Tori spherical dish end welded with flange, manual lid lifting with davit arm
Flange	: 18 mm thick SS 316 -2 Nos. welded
Jacket	: 4 mm thick SS 304 with spiral stiffeners
Gasket	: Silicon
Insulation	: 50 mm thick mineral wool duly cladded with 14 SWG SS 304 sheet
Legs	: 4 Nos. SS 304 pipe with base plate

*** To be specified and confirm by the supplier as per their equipment design**

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Vessel Connections :	
Hand hole	: 150 mm dia with hinge type lid and silicon "O" ring



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Light glass	:	4" dia with flange
Sight glass	:	4" dia on hand hole Lid with wiper
Vacuum Inlet (VI/VB/CG)	:	1 ½" dia TC end
CIP connection	:	2"x1" dia TC 1 no. with common header for spray ball
Product temperature	:	1½" dia TC end at bottom of vessel
Product outlet	:	Flush bottom valve
Anchor Stirrer	:	On center of top dish
Product recirculation	:	1½" dia TC end (On top of dish)
Product temperature	:	1½" dia TC end *
Product outlet	:	Flush bottom valve*
Vessel Design parameters :		
Working temperature	:	30 to 125 degree C.
Design Temperature	:	20 to 135 degree C.
Working pressure	:	-1 to 2 kgs/cm sq.
Design pressure	:	-1 to 2.25 kgs/cm sq.
Hydro test pressure	:	-1 to 3.0 kgs/cm sq.

*** To be specified and confirm by the supplier as per their equipment design**



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DESCRIPTION	
(To be specified by the supplier, if any variation)	
Jacket Design parameters :	
Working temperature	: 35 to 135 degree C. *
Design Temperature	: 25 to 150 degree C. *
Working pressure	: 3.5 to 4 kgs/cm sq. *
Design pressure	: 4.0 to 4.5 kgs/cm sq. *
Hydro test pressure	: 5.5 to 6.0 kgs/cm sq. *
Jacket nozzles connections	: For Steam inlet, cooling water outlet, pressure gauge etc. 1½"dia TC end
Miscellaneous details	
Agitator	: Anchor type semi-contra designed with Teflon scrapper and self-adjusted
Motor	: 1 HP /1440 rpm
Gear Box	: 30:1 ratio
Shaft seal	: Oil seal
Accessories:	
VFD	: Anchor Stirrer and Homogenizer
Compounding gauge	: Diaphragm type
Temperature sensor	: TC end 0 to 250 degree C with class A accuracy
Spray ball	: 360 degree rotating type

*** To be specified and confirm by the supplier as per their equipment design**



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DESCRIPTION	
(To be specified by the supplier, if any variation)	
4) Storage Vessel	
Capacity	: Working : 100 to 120 liters (100 Kgs) : Gross : 150 to 160 liters *
MOC	: Contact parts : SS 316 Non-contact parts : SS 304
Specific gravity	: 0.9 gm/cc *
Shell	: 2.0 mm thick SS 316 cylindrical
Bottom	: 2.0 mm thick SS 316 conical dish end welded with shell
Top	: 1.5 to 2.0 mm thick SS 316 loose lid with 1/3 rd open hinged type with gasket and clamp
Legs	: 3 Nos. SS 304 pipe with cross support and nylon castor wheel
Vessel connection	: Air vent : 1½" dia TC at top Outlet : 1½" dia TC with manual butterfly valve
Vessel Design parameters :	
Design temperature	: 4 to 50 degree C. *
Working Temperature	: 4 to 40 degree C. *
Working pressure	: Ambient *
Design pressure	: Water fill *
Vent filter	: 5 micron SS sintered filter 1.5" dia TC end

*** To be specified and confirm by the supplier as per their equipment design**

DESCRIPTION
(To be specified by the supplier, if any variation)
WATER RING VACUUM PUMP



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Type	:	Water ring
Motor	:	3HP/Non FLP/Foot Mounted *
Mounting	:	On Skid
Flow rate	:	50 cfm *
Ultimate Vacuum	:	710 mm of HG *
Water inlet flow required	:	7 liters per minute with pneumatic actuator valve and flow sensor.
CIP RE-CIRCULATION PUMP		
Capacity	:	200 liters CIP tank with pump
Pump	:	1HP/Non FLP *
Flow rate	:	50 LPM*
Scope of supply	:	To clean vessels and pipe line with re-circulation & CIP drain with conductivity sensor, transmitter, valves & pipe line etc.
MANUFACTURING VESSEL TO STORAGE VESSEL PUMP		
❖ Lobe Pump		
Capacity	:	Max 1000 Kgs per hour depending upon product viscosity *
Pump	:	1.5 HP, 960 RPM, 3 Phase, 415V *
Construction	:	Aluminum Casting Body with powder coated. Internal Contact parts SS316 and non-contact parts SS304

*** To be specified and confirm by the supplier as per their equipment design**

DESCRIPTION		
(To be specified by the supplier, if any variation)		
STORAGE VESSEL TO FILLING HOPPER LINE		
❖ Lobe Pump		
Capacity	:	Max 500 Kgs per hour depending upon product



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		viscosity *
Pump	:	1.5 HP, 960 RPM, 3 Phase, 415V *
Construction	:	Aluminum Casting Body with powder coated. Internal Contact parts SS316 and non-contact parts SS304*
❖ High & Low-level sensor input to be considered in the PLC.		
The plant must include the following:		
<u>Interconnecting pipes</u>		
<ul style="list-style-type: none">➤ All internal connecting pipe line between manufacturing vessel, wax vessel, water vessel and transfer storage vessel with manual butterfly valve and with TC joints.➤ The vessels should be provided with essential safety valve, pressure gauge and vent ball valve etc. required as per design.➤ Hydraulic oil and Gear oil etc. to be provided as required.➤ Inline conical filter should be provided for the transfer of components to manufacturing vessel from wax vessel and water vessel.		
SS Working Platform :		
Should be made out of SS 304 square pipe frame work with 3mm SS 304 dimple sheet with ladder and railing.		
<ul style="list-style-type: none">• Room height is 3000 mm only		

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ANNEXURE - V : THIRD PARTY INSPECTION



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DESCRIPTION

(To be specified by the supplier, if any variation)

Introduction:

The inspection of ointment manufacturing plant vessels by TPIA mentioned below.

- 1) Manufacturing Vessel
- 2) Wax Phase Vessel
- 3) Water Phase Vessel
- 4) Batch Storage Vessel

Preferred TPIA:

- Intertek, Bureau Veritas, TUV India

Scope of work:

- Involvement of TPIA in the Design, Verification of Materials, Fabrication, Inspection, Testing of vessels.

Design:

Vendor shall design the tanks based on the capacity mentioned and as required. The design including calculation and drawings shall be appraised by TPIA engaged by vendor.

- i) Fabrication of the vessel as the requirement mentioned in the URS in detail.
- ii) Preparation of detail procedures for welding (WPS & PQR), Fabrication, NDT, Hydro & Pneumatic testing, integration with Road Tanker trailer etc., including QAP schedule & PERT charts. The above procedures shall be approved by TPIA & Purchaser.
- iii) Procurement & testing of raw materials as per QAP.
- iv) Fabrication & testing shall be as per details given in the specification.
- v) Preparation & submission of final document: production master file, Radiography films, etc.



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DESCRIPTION

(To be specified by the supplier, if any variation)

Note:

- Width of SS Sheets shall be chosen to minimize No. of cirseam welds (more than or equal to 2 mtr).
- Each end dome shall be made out of maximum number of two Sheets preferably.
- If the design calls for lower thickness than minimum thickness specified above, the thickness specified above shall be provided. During design, if higher thickness is required than the minimum thickness specified above, higher thickness shall be provided. The same shall be considered while bidding.

Fabrication Details:

WELDING, WELDER & WPQ:

- 100% TIG welding, shall be carried out by Argon Arc process, right from root to final passes for all butt welds (Long seams, 'C' seams, nozzles, pipe to flange joints) and all internal and external welds including fillet welds.
- Welding consumables (filler wire) shall be used as per AWS classification for SS welding. Filler shall be IGC tested.
- Dye penetrant test shall be carried out for root and final passes of all types of welds.
- Radiography: 100% on butt-welded joints including nozzle pipe to flange joints or TC joints. All welds other than butt welds shall be DP tested. Radiography for all butt welds by X- ray machine with 2-2T sensitivity as per ASTM E-94.
- After hydrotest, the vessel has to be degreased, pickled and passivated and fitment of all flow components and replacing of all gaskets and fasteners.
- Total fabrication shall be carried out in the presence of TPIA engaged by vendor as per the scope given in QAP.



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DESCRIPTION

(To be specified by the supplier, if any variation)

Testing:

Testing of materials:

- Materials of construction shall be as given in part No. 4.9 Table: 1 all materials used shall be tested as per Code in the Reputed Govt. approved testing labs before fabrication. All the material proposed to be used for fabrication of tank, shall be tested in presence of TPIA for mechanical, chemical and IGC tests as per A- 262 Practice-E in addition to availability of Mill test certificates.
- Sheet used for the fabrication of the tank shall be procured with 100% ultrasonic testing shall be carried out as per Practice ASTM A-435 duly witnessed by TPIA.
- If the Sheets procured by the vendor were UT tested but the same was not witnessed by TPIA at manufacturer site, 100% UT testing of Sheets need to be carried out at fabricators shop in presence of third party inspection agency prior to taking up the vessel fabrication.
- Test on ferrite number of weldments shall be carried out to ensure within 3% to 12%. Test certificates shall be furnished to purchaser for approval.
- Pneumatic Gross Leak Test: The tanks shall be tested at 3.0 bar (g) using dry Nitrogen gas for gross leaks prior to Hydro test.
- Hydraulic Pressure Test: with DM water having fluoride content less than 25 PPM shall be carried out at 1.5 times the design pressure as per ASTM A 530.

Note: Before hydraulic test, the internal surfaces of the tanks shall be mechanically cleaned.

- Pneumatic Leak Test: After Hydro test of the tanks, the tanks shall be tested at 3.0 bar (g) using dry Nitrogen gas with dew point of minus 40 Deg. C or better and leak check with soap solution.
- Material of construction of tanks shall be strictly as mentioned in the URS.



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DESCRIPTION

(To be specified by the supplier, if any variation)

GENERAL CONDITIONS:

- 1) Vendor shall submit the offer in two parts-techno commercial and price bid:
 - ❖ Along with the offer:
 - Filled in checklist as per Checklist-III.
 - Compliance for tender specifications including General conditions.
 - Deviations if any with justifications.
 - After receipt of order
 - Detailed QAP.
 - Design calculations.
 - Drawings and procedures for approval.
 - Along with supply:
 - Production Master file (3 copies) consisting of Design calculations, as built drawings, BOM, test reports, fabrication procedures, HT & SR charts, TPIA certified documents, rub-off,
 - All radiography films.
 - Soft copy of as-built drawings.
- 2) Third Party Inspection Agency charges shall be quoted separately.
- 3) All the testing charges like UT of Sheets, IGC, mechanical & chemical testing, etc., shall be included in the offer.



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DESCRIPTION

(To be specified by the supplier, if any variation)

CHECKLIST-I

SCOPE OF INSPECTION: AS PER QAP

The vessel should be fabricated under the inspection of Third party/Purchaser representative as per QAP

QUALITY ASSURANCE PLAN (QAP)

Sl. No.	Characteristics / type of check	Ref. Document	Method of check	Quantum of check		
				Manufacturer QC	Third party	Purchaser
1.a	Identification of material with Mill T/C & witness of Physical, IGC Test for Sheets.	As per PO	Visual	100% H	100% R	R
1.b	Witness of Physical & IGC Test for pipes, fittings, gaskets, flow components etc.,	As per PO	Visual	100% H	100%W	R
1.c	Ultrasonic Testing of Sheets * (refer note in specifications)	As per PO	Visual	100%W	100%W	W/R
2	Review of fabrication drawings and Design Calculation	As per PO/ drawing	Material as per design	100% H	100% R	R
3	Review of welding procedure & Qualification	AWS	Review	100% H	100% R	R
3.a	Welder Qualification	AWS	Review	100% H	R	R
4	Checking of root run & final weld by dye Penetrant test (butt welds)	As per PO	Visual	100% W	100% R	R
4.a	Measuring of Ferrite Number in all weldments	As per PO	Checking with meter	100% W	W	R
5	*Marking of nozzle orientation	As per drawing	Location of nozzle	100% W	100% W	R/W
6	Dye Penetrant test on all fillet welds.	As per PO	Visual	100% W	100% R	R
	Visual & Dimensional	As per	Dimension			



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7	inspection	approved drawing		100% W	100% W	R
8	Shell rolling, long seam & Cir.Seam fit up	As per std	Visual	100% W	100% W	R
9	Back gouging of long & cirseam welds.	As per std	Visual	100% W	100% R	R
10	Circularity of shells after rolling	As per std	Visual	100% W	100% W	R
11	Forming of dished ends	As per std	Visual	100% W	100% W/R	R
12	Fit up of nozzles, saddles and supports and welding	As per std	Visual	100% W	100% W	R
13	Evaluation of radiography films of all butt welds	As per PO	Film evaluation	100% W	100% R	R
14	*Stress relieving of total fabricated tank	As per PO	Graph	100% W	100% W	R
15	Mechanical cleaning and buffing	As per PO	Visual	100% W	100% R	W/R
16	* Hydraulic test for tanks as per design code	As per PO	Pressure hold method	100% W	H/ W	W
17	* Pneumatic leak test for tanks	As per PO	Pressure hold method	100% W	H/ W	W
18	Pickling and passivation	As per PO	Visual	100% W	R	R
19	Filling with dry nitrogen at 0.5bar (g)	As per PO	Gauge reading	100% W	R	R
20	Stamping of the vessel and issue of the certificates	As per PO	Visual	100% R	100% W	---
21	Production Master File	As per PO	Document	100% R	R	R
22	Dispatch clearance	As per PO	Document	-	-	H

Legend: R – Review, W – Witness, H – Hold.

Note: The purchaser reserve right to participate in the Inspection at any of stage fabrication & the bidder shall intimate the work progress periodically. However, purchaser will witness the activities marked as "*" if required.

DESCRIPTION

(To be specified by the supplier, if any variation)

CHECKLIST-II

PROCEDURE FOR PICKLING & PASSIVATION



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Mechanical Cleaning:

All metallic surfaces inside and outside having scales and foreign materials and all welded surfaces have to be cleaned. This can be done by scrubbing with metallic brush (Stainless Steel). The loose scales and powders obtained from the above process can be cleaned by blowing, sucking or washing with water. Mechanical cleaning shall be carried out before stress relieving.

Degreasing, pickling and passivation:

Degreasing, pickling and passivation shall be carried out as per the following method for the tank after hydro testing.

Swabbing method using Barium Sulphate as an acid carrier for both inner and outer surfaces of the tanks.

Degreasing has to be done by soaking with hot detergent solution of Lissapol at 60 Deg. to 70 Deg. C for at least 2 hours till satisfaction.

Pickling and Passivation (Swabbing Method)

The pickling and passivation is done with barium Sulphate as carrier (chloride levels 25 PPM) in the form of paste. For each of pickling and passivation operations, the paste has to be applied on the surface and has to be kept for at least two hours. Paste has to be removed with waste cotton in each operation and finally the surface has to be rinsed with DM water.

Note: If suppliers desires to adopt filling method for pickling & passivation of inner surface of the tank the same may be adopted with the approval from the purchaser.

Checking

All the relevant tests shall be carried out to ensure proper pickling and passivation as per ASTM A 380.

Drying

The drying is done to remove water and this is done as given below:

Passing dry Nitrogen /Air having dew point less than -40 Deg. C and free from oil and grease (less than 10 PPM) at 60 Deg. C till the moisture level at the exit comes to the inlet concentration value.

DESCRIPTION

(To be specified by the supplier, if any variation)

CHECKLIST-III

CHECKLIST TO BE FILLED BY THE BIDDER

Sl.No.	Description	Vessel
1	Design code followed	



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2	Design pressure considered	
3	Stress value considered at Design temperature for design of tanks	
3.1	100% UT of Sheets as per ASTM A435 (If done at plate mfg. Plant, with TPIAwitness)	
4	Allowance considered: i) Corrosion allowance	
5	Thickness selected (a) shell(including CA) (b) dish	
6	Material of Construction as per URS	
7	Welding 100% by GTAW process	
8	Width of storage tank Sheets 2 mtrs (Minimum)	
9	Radiography: (100%) X-ray machine with sensitivity of 2-2T	
10	Mechanical cleaning	
11	Degreasing, Pickling & passivation	
12	Hydro testing of the tanks	
13	Pneumatic testing of the total vessel	
14	Third party Inspection agency	
15	Third party inspection charges quoted separately	
14	Acceptance of QAP	
15	Accepting part order	

ANNEXURE - VI : ELECTRICAL DETAILS

DESCRIPTION

(To be specified by the supplier, if any variation)

Standard Operating Frequency	:	50 Hz
Standard Operating Voltage	:	230 / 415V*
Total power consumption	:	*
Motor Details with rpm	:	*



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Gear Box Details (If any)	:	*
PLC and HMI details	:	*
VFD details (If any)	:	*
Tower lamp	:	*
Starter	:	*
Major Cabling details		
For Main supply (In client's scope)	:	
For Main drive motor	:	*
End connection details	:	MCB or Socket should be with equipment
Earthing requirement	:	Arrangement should be with system
An Isolator Circuit breaker	:	To be supplied with machine at power supply in point of appropriate capacity by vendor. *
Cable length with equipment	:	*
<i>Any other detail not mentioned above, also to be included.</i>		
<i>Client will provide & connect the required cable in to vendor's panel. From machine panel to machine and its other accessories to be supplied and connected by vendor at site.</i>		

*** To be specified and confirm by the supplier as per their equipment design**



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DESCRIPTION

(To be specified by the supplier, if any variation)

Power Panel : (NON FLP)

Scope	:	Should be made of SS 304 sheet with following : <ul style="list-style-type: none">• All contractor• Relay• MCB• PLC /Analog inputs• Output card• VFD• Modbus communication• HMI cable from PLC to HMI for automation etc.
-------	---	--

Remote Panel :

Scope	:	Should be made of SS 304 sheet with following : <ul style="list-style-type: none">• Touch screen 10" IPC• Emergency & Key switch• Auto/Manual function selection etc..
-------	---	--

SCADA SYSTEM :SCADA software with 2000 Tags lab view /Dell make PC with 1 TB hard disk 4 GB RAM with USB port , key pad ,mouse etc.

Controls for manufacturing vessel: Following controls to be consider :

- Total weight of the product
- Heating temperature of the product
- Mixing time and mixing speed for Anchor
- Mixing time and mixing speed for Homogenizer
- Re-circulation product time ,CIP re-circulation time
- Cooling temperature of product
- CIF flush and with conductivity sensor



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DESCRIPTION

(To be specified by the supplier, if any variation)

Miscellaneous :

- ❖ Wiring between Panel and the Machine should be in the Scope of Vendor. The exact measurements shall be taken by visiting the site.
- ❖ The Incomer to the Operating Panel shall be provided by HOMCO, however any Cable Trays or SS 304 Conduits required for the same shall be provided by the Vendor.
- ❖ Cable routing from Operating Panel to the Machine shall be done as per cGMP i.e. routing through Cable Trays outside Clean Room Areas and SS 304 Conduits inside Clean Room Areas.
- ❖ All the Component Makes should match the Approved Makes list provided.
- ❖ Any deviation from this should be documented and communicated to HOMCO.
- ❖ All Calibration Certificates are to be produced during Installation of Machine, without which the Installation is deemed incomplete. All the Certificates should be Traceable to National / International Standards.
- ❖ The Validity of Calibration shall be minimum 9 months and maximum 12 months from the date of Installation.
- ❖ All the Signal Cables should be shielded to avoid interference.
- ❖ Complete Earthing of Equipment.
- ❖ Complete covering of Electrical Cables and Other Connections.

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - VII : SAFETY FEATURES

DESCRIPTION
(To be specified by the supplier, if any variation)
Interlock Control:
<ul style="list-style-type: none">➤ If vacuum pump is on hydraulic power pack ,motor should not start➤ If hydraulic cylinder in lift condition, Anchor and Homogenizer motor should not start.➤ If flow of cooling water in mechanical seal of stirrer is not proper , switch off of stirrer through flow switch➤ When steam valves are in operation, cooling valve should not function➤ If air pressure low ,hooter should blow and indicate in PLC➤ If temperature over shoots, hooter should blow and inlet valve should off
The equipment should be provided with motor overload safety relay.
In the event of equipment malfunction or stoppage of utilities, the unit must contain all necessary protection devices to ensure that equipment and product remain in safe condition.
Equipment settings should not get disturbed due to power failure. Equipment should not restart without human intervention.
Equipment should indicate fault through audio / visual signal with details on Control panel (Failure mode detection)
An easily accessible emergency stop to be provided on main control panel door.
Lubricant should not come in product contact.
Wherever possible, warning symbols should be provided.
Electrical wiring must be concealed

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - VIII : UTILITY REQUIREMENT

DESCRIPTION	
(To be specified by the supplier, if any variation)	
Vacuum	: *
Compressed Air	: Ordinary * Non Lubricated *
Water	: *
Chilled Water	: *
Nitrogen	: *
Cooling water	: *
Steam	: Pure Steam * Raw steam *
Any other	: *

*** To be specified and confirm by the supplier as per their equipment design with pressure and flow rate and pipe size require..**



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ANNEXURE - IX : CLEANING TECHNIQUE

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Mode of machine cleaning	:	*
Use of Lubricants	:	*
All contact parts should be easily dismantled and cleanable.		
Easy washing and cleaning facility should be available (Details of CIP to be provided)		
Drain points: Vendor should specify the pipe size and location of drain points required as per systems drain requirement *		

ANNEXURE - X : MECHANICAL DETAILS

DESCRIPTION		
(To be specified by the supplier, if any variation)		
Dimension (In mm)	:	*
Net Weight (In Kgs.)	:	*
Type of Packing	:	*
Case Dimension (In mm)	:	*
Gross Weight (In Kgs.)	:	*
Foundation details (If required)	:	*

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - XI : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL ITEMS

DESCRIPTION

(To be specified by the supplier, if any variation)

- Optional Items (If any , Vendor should provide the list with rate) *
- Recommended Spares along with list & quantity (Vendors should submit with tender) *
- If any items required but not included in URS , to be mentioned and submitted with unit rate and quantity * (And it can be indicate during pre-bid meeting)

Details of Bought out components to be specified.

Any other ancillary or accessories or optional items not mentioned above also to be quoted.

*** To be specified and confirm by the supplier as per their equipment design**

ANNEXURE - XII : TRAINING REQUIREMENT

- Training to all concern of M/s. HOMCO, Kerala for the Installation, Operation, Maintenance and Cleaning of all the Equipment included in the Ointment Manufacturing Plant shall be provided by vendor and training record will be documented.
- Vendor shall support client in execution of all the Qualification Phases.



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ANNEXURE - XIII : APPROVED MAKES

Stainless Steel Sheet & Pipe: Tata / Jindal	:	*
Motor: Siemens / Bharat Bijlee / Hindustan / Bonfiglioli / Panasonic	:	*
Servo Motor & Drive: Siemens / Allen Bradely / Delta / Panasonic	:	*
PLC: Siemens / Allen Bradely / Delta	:	*
Gear Box: Bonfiglioli / Panasonic / Premium	:	*
HMI: Siemens / Allen Bradely / Delta / Exor	:	*
Vacuum Pump: Indovac / PPI / Promivac Engineers	:	*
Lobe Pump: Unique Pump / Alfa Laval	:	*
VFD: Schnieder / ABB / Siemens / Allen Bradely / Delta	:	*
FRL Unit & Pressure Switch: Festo / Euroswitch / SMC	:	*
Sensor: Baumer / Sick / P&F / Panasonic / Leuze / Radix	:	*
Load Cell: Precia Molen / Mettler Toledo	:	*
Shaft Seal: Hi-Fab / Leak Proof	:	*
Encoder: Kubler / Baumer / Fraba	:	*
Cables: Finolex / Polycab	:	*
<p>❖ Any other components, not mentioned above, to be specified by the vendor.</p> <p>❖ All the Component Makes should match with the Approved Makes listed above. Any deviation from this should be documented and communicated to HOMCO and Pharma Consultant.</p>		

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - XIV : DOCUMENTATION

List of all Documents to be supplied along with equipment [AS APPLICABLE]			
Sr. No.	Document to be supplied	Qty	Remarks
1	Design and operational qualification	2 sets	
2	SAT/FAT procedures	2 sets	
3	Operation manual	2 sets	
4	Maintenance manual	2 sets	
5	Spare parts manual	2 sets	
6	All engineering drawings	2 sets	
7	List of instruments	2 sets	
8	Calibration certificates	2 sets	
9	Warranty / Guarantee	2 sets	
10	List of all components with referencing	2 sets	
11	Civil foundation drawings	2 sets	
12	Pre installation requirements	2 sets	
13	Installation requirements	2 sets	
14	Installation manual	2 sets	
15	Technical literature, data sheets and equipment catalogues	2 sets	
16	DQ, IQ, PQ documents.	2 sets	
17	Calibration Report of all sensors, controllers, PLC, transmitters, indicators etc.	2 sets	
18	Test Certificates of all material of construction	2 sets	
19	Test Certificates of the software used in machine control / monitoring system.	2 sets	

ANNEXURE - XV : TERMS AND CONDITIONS



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Delivery Period	:	*
Payment Terms	:	As mentioned in tender.
Packaging and Forwarding	:	By Vendor
Un-loading at site	:	By vendor /Supplier (If required, help for the arrangements of unloading can be done by client) Installation in position by the vendor under the client's supervision
Excise / Taxes /GST	:	*
Material for Trial arrangement	:	* (To be arranged by client)
Installation and Commissioning	:	By Vendor
Submission of documents and drawings		
Response to URS and submission of quotation	:	Within 1 week
Submission of detail functional design specification and schematic drawings	:	Within a week after order finalization
Submission of FAT / SAT specification	:	2 weeks before FAT
Submission of IQ AND OQ documents	:	With equipment delivery
Drawings / diagrams	:	Within a week after receiving PO
The supplier should notify customer 2 weeks in advance of the beginning of FAT		
Catalogue, Equipment drawing, List of clients and year of establishment to be submitted alongwith quotation.		
<i>Any other terms, not mentioned above, also to be specified.</i>		

*** To be specified and confirm by the supplier as per their equipment design**



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ANNEXURE - XVI : ABBREVIATION

1.	URS	:	User Requirement Specification.
2.	HOMCO	:	Kerala State Homeopathic Co-operative Pharmacy Ltd.
3.	DQ	:	Design Qualification
4.	IQ	:	Installation Qualification
5.	OQ	:	Operational Qualification
6.	PQ	:	Performance Qualification
7.	SS	:	Stainless Steel
8.	RHS	:	Right Hand Side
9.	MOC	:	Material of Construction
10.	KW	:	Kilo Watt
11.	HP	:	Horse Power
12.	RPM	:	Rotation Per Minute
13.	FLP	:	Flame Proof
14.	cGMP	:	Current Goods Manufacturing Practices
15.	O&M	:	Operation and Maintenance
16.	GA	:	General Arrangement
17.	SLD	:	Single Line Diagram
18.	HOD	:	Head of Department
19.	QA	:	Quality Analysis
20.	MRP	:	Maximum Retail Price
21.	NMT	:	Not more than
22.	VFD	:	Variable frequency drive

Any other details, not mentioned in Annexure I to XV, to be specified in the quotation/specification by the vendor.