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### Supplier's Copy

# USER REQUIREMENT SPECIFICATION

Name of the Company		ANNEXURE - 1 : BABIG
		288G
	1	(To be specified by the
Contact Person	ini s	Scope : Suppl
all interconnecting piping, pum	ristw	Plant
Address		la adi
Contact Details	HOH .	VM to
n Manufacturing Haut (Steam bow	1000	Macrific Solidary Solidary
Department	:	Ointment - (Ground Floor)
Equipment and Code No.	al Gibă	Ointment /Cream Manufacturing Plant
* 21831 dS 1 o	BESC I	Could be a second of the secon
Name of work		
Name of work	Date:	Validation of cGMP model Ointment/Crean
Name of work - *and 0 at 0 a	iso anutac ax Ver	Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMC
Name of work - *and 0 at 0 a	iso anutac ax Ver	Validation of cGMP model Ointment/Crean
turing Vessel seel essel	Dall mulac ax Ves ater V	Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
turing Vessel seel essel	Ibo mulac ax Ves ater V	Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
turing Vessel seel essel Vessel Pume (2 Ness) No.	inutati ax Vela ater V orage on the	Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCG – Kerala
turing Vessel essel vessel vessel essel essel vessel esel vessel ee Pume (2 Nes) Pemp	ibd mufac ax Ves ater V or ug en ca ansig	Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCG – Kerala
turing Vessel essel essel Vessel be Puma (2 Nes) Pump and	sad ax Ves ater V orage orage anside accidente	Validation of cGMP model Ointment/Crear Manufacturing Plant – 100 KG at M/s. HOMCG – Kerala
turing Vessel seel essel essel vessel oe Puma (2 Nos) Pump and platform platform panel	sad ater V orage orage anale anale te con orange	Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
Ref. No.  Pemp 200 Pemp (2 Nes)  Pemp 200 Pemp 2	sad ax Ves ater V or spr anala anala texan texan ontrol bases	Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCO – Kerala  To take the plant of the plan
Ref. No.  Ref. No.  Pamp and pattern plants and panel	tati ax Ves ater V or 19 and tak and tak and tak ontrol base base	Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala



CONSULTANT: M/S. KNACK TECHNOCRATS

111, AVINASH, 7 BUNGALOWS, J.P. ROAD, ANDHERI (W), MUMBAI – 400 05: TEL. NO.: 022-2636 1629, Email: infoknack@gmail.com

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# DINTMENT/CREAM MANUFACTURING PLANT - 100 Kgs (STEAM HEATED)

ANNEXURE - I BASIC DETAILS MACHINE

(To be s	рес	<b>DESCRIPTION</b> ified by the supplier, if any variation)
Scope	:	<ul> <li>Supply, Installation, Commissioning &amp; Validation of cGMP model SS 316 Ointment - CREAM 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 -Kerala</li> </ul>
Machine	:	Ointment/Cream Manufacturing Plant (Steam heated plant)
Model	:	Department Collins
Туре	:	*
Capacity (In litres)	:	Working: 100 kgs *  Net : 120 to 125 liters *  Gross : 150 to 160 liters*
The Main plant Consist of		1) Manufacturing Vessel 2) Wax Vessel 3) Water Vessel 4) Storage Vessel 5) Twin Lobe Pump (2 Nos) 6) Transfer Pump 7) Vacuum Pump and 8) Interconnecting piping 9) Working platform 10) 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

: CGMP FEATURES PROCESS CONTROL

AND IV

OPERATIONAL FEATURES

th hinge type lid and silicon 'C' ri		DESCRIPTION Slord brish
( To be sp	pecif	ied by the supplier, if any variation)
1) Manufacturing Vessel	gec	Sight glass 1 4° dia Flan
Capacity bend nommed driw .com	•	Working: 120 to 125 liters (100 Kgs)  Gross: 150 to 160 liters *
MOC * on 1	bne	Contact parts : SS 316 Palliment France   Non-contact parts : SS 304
Specific gravity	d io	0.9 gm/cc * and some state of the control of the co
Shell * (daib to got nO) b	<b>19</b> 0	5.0 mm thick SS 316 cylindrical with flange *
Bottom	115	5.0 mm thick SS 316 conical dish end welded with shell*
genizer by Tee connection*  qoT  & Stator tyne, Skid, counted	enio Loto	5 mm thick SS 316 Tori spherical dish end welded with flange *
Flange and publication in (9.	-	16 mm thick SS 316 -2 Nos. welded *
Jacket	108	4 mm thick SS 304 with spiral stiffeners*
Gasket	:	Food Grade Silicon Gasket*
Insulation	ps <b>i</b> b	50 mm thick mineral wool duly cladded with 14 SWG SS 304 sheet *
Legs pan		4 Nos. SS 304 pipe with base plate to suit load cell bracket*
Load cell Page 1990		4 Nos. , 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

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роктиоо аваром взяцт.		DESCRIPTION fied by the supplier, if any variation)
Vessel Connections :		
Hand hole	2 75	150 mm dia with hinge type lid and silicon 'O' ring*
Light glass (notation vac in the	lg is	4" dia with flange*
Sight glass	:	4" dia Flange on hand hole Lid*
Vacuum Inlet	01	1 ½" dia TC end*
CIP connection * angli 0 ar or	081	2x1" dia TC 1 nos. with common header for spray ball*
Pressure Transmitter	æ	1½" dia TC *
Extra nozzle 400 22 25		1" dia TC end -1 no. *
Anchor Stirrer		On center of top dish*
Product recirculation	Хŧ	11/2" dia TC end (On top of dish) *
Product temperature	ж	1½" dia TC end *
Product outlet	2 18	Through homogenizer by Tee connection*
Homogenizer	ek S	In line, Rotor & Stator type, Skid mounted,*HP/2800 rpm/415 V (FLP) for re-circulating the material back into the vessel and used to transfer product mounted at the bottom *
Vessel Design parameters :	12 5	Gasket : Food Grad
Working temperature	*5	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	niii	-1 to 3.0 kgs/cm sq. *

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		DESCRIPTION
( To be	specif	fied by the supplier, if any variation)
Jacket Design parameters :		Accessoriest
Working temperature	191	35 to 135 degree C. *
Design Temperature		25 to 150 degree C. *
Working pressure	:	4 kgs/cm sq.Working. *
Design pressure	16 01 9	4.5 kgs/cm sq. *
Hydro test pressure	(HUE)	5.5 to 6.0 kgs/cm sq. * gms_l lesseV
Jacket nozzles connections	: 6) 108	For Steam inlet, cooling water outlet, pressure gauge etc. 1½"dia TC end
Miscellaneous details		midner of angeld
Agitator	EL 106	Anchor type semi-contra designed with Teflon scrapper and self-adjusted*
Stationary Baffles	61/06	2 stationary baffles for breaking mass movement and push the mass on center*
Motor state amed earneb -	- <b>:</b>	*HP /415 V/TEFC 1440 rpm (HMM Make-FLP). *
Gear Box		30:1 ratio *
ted BFV or Assembly with Liclass Thanks pack unit & PLE motor	as lpA	Dry mechanical seal (Hi – Fab/Leak proof).Cartridge type double acting mechanical seal (Hi- Fab /Leak Proof) with cooling arrangement. For safety of mechanical seal flow switch is provided. *
Vessel Welding	20 W L	Vessel is argon arc welded & smooth grinding finish from inside & outside.
Vessel Finish		Internally: 0.5 Ra. 240 grit Mirror polish) Externally: 0.8 Ra. 180 grit. (Matt finish)



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		DESCRIPTION
( To be	specif	fied by the supplier, if any variation)
Accessories:		se are the dampage surery
VFD	<u> </u> :	Anchor Stirrer and Homogenizer
Compounding gauge	:	Diaphragm type
Pressure sensor	<b>i</b>	1 to 5.0 kgs/cm sq.
Spray ball	103 G	360-degree rotating type
Vessel Lamp	2 3	LED Lamp (FLP)
Sight glass with Wiper		100 mm dia
Vacuum Inlet	bine.	Pneumatic actuated BFV
Vacuum breaker with Filter		Pneumatic actuated BFV
Steam inlet/Condensate		Pneumatic actuated Valve with steam trap
Cooling Inlet/ Outlet		Pneumatic actuated Valve with jacket drain
Temperature sensor		TC end 0 to 250 – degree temp with class 'A' accuracy & Transmitter
CIP Inlet   #sed/ds8 = (H) last	s prins	Pneumatic actuated BFV
Hydraulic lifting arrangement		To lift top Agitator Assembly with Lid 500mm ht. including Hydraulic Power pack unit & FLP motor.
Load cell 4 Nos.		For vessel legs with junction box & FLP digital weights indicator with 0.05% accuracy least count 500gms in total volume
Ra. 240 quit Minor polisis	F (+:	S.S 304 damed beast
CIP		CIP Drain & Utility header along with 2 Nos.Pneumatic actuated BFV valve.

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



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	(T9.	
	ecif	ied by the supplier, if any variation)
2) WAX Vessel		Vessel Connections :
Capacity	19 O	Working: 50 to 60 liters ( 50 Kgs)  Gross : 75 to 85 liters
MOC	r <b>e</b> 8	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	09.0	4.0 mm thick SS 316 Elliptical dish end welded with shell
Тор	PU\$2	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	SDX	4 mm thick SS 304 with spiral stiffeners
Gasket	:	Food Grade Silicon Gasket 190 mgies G 1990st
Insulation	98)	50 mm thick mineral wool duly cladded with 14 SWG SS 304 sheet
Legs	90	4 Nos. SS 304 pipe with base plate to suit load cell bracke
Vessel Connections:	95/0	Viorking pressure : 3.5 to 4 k
Hand hole	91	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.
Vacuum Inlet/VB/CG	:	1 1/2" dia TC end connections salvasi 1 1/2"
CIP connection	:	2"x1" dia TC 1 Nos. with common header for spray ball
Anchor Stirrer	85	On center of the top dish as belliosee ad of *

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



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NO		DESCRIPTION
( To be sp	pecif	ied by the supplier, if any variation)
Vessel Connections :		'purphatika k
Product temperature	3 25	1½" dia TC end
Product outlet	S : 115	Flush bottom valve
Vessel Design parameters :	4.13	dino-nali
Working temperature	ı	30 to 125 degree C.
Design Temperature	NŠRI	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 :	12 3	Gasket 4 Food Grad
Working temperature	1	35 to 135 degree C. *
Design Temperature	i	25 to 150 degree C. *
Working pressure	:	3.5 to 4 kgs/cm sq. *
Design pressure		4.0 to 4.5 kgs/cm sq. * Slott bnsH
Hydro test pressure	n.n	5.5 to 6.0 kgs/cm sq. *
Jacket nozzles connections		For Steam inlet, cooling water outlet, pressure gauge e

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NO		DESCRIPTION
		ied by the supplier, if any variation)
Miscellaneous details	nc r	: polytoW -x
Agitator endition	150	Anchor type semi-contra designed with Teflon scrapper and self-adjusted
Motor are 321	aht	* HP /415 V/1440 rpm (FLP)
Gear Box 408 88 1 2ths	q io	30:1 ratio
Shaft seal	i	Specific gravity i Class IIO
Vessel Welding	яŝн	Vessel is argon arc welded & smooths grinding finish from inside & outside.
Vessel Finish	ioinie	Internally: 0.5 Ra. 240 grit (Mirror polish)  Externally: 0.8 Ra. 180 grit (Matt finish)
Accessories:	2 AD	Tep Smm this
SS 316 -2 Nos. welded	13130	Anchor Stirrer and Homogenizer
Compounding gauge	8 SI	Diaphragm type
Temperature sensor	sket	0 to 250 degree C with class A accuracy & Transmitter
Spray ball and your learning	افد	360-degree rotating type 3 Nos.
Vessel lamp	:	LED Lamp (FLP)
Sight Glass with wiper	:	100 mm dia
Steam Inlet/Condensate		Pneumatic actuated Valve with steam trap
CIP Inlet	:	Pneumatic actuated BFV
Lid Lifting arrangement		Manual with davit Arm
CIP		CIP Drain& Utility header along with 1 Nos. Pneumatic actuated BFV valve

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



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	PTIO	
•		fied by the supplier, if any variation)
Capacity bengiseb someo-in	19 30	Working: 120 to 125 liters (100 Kgs)  Gross: 150 to 160 liters *
MOC mg1 0		Contact parts : SS 316  Non-contact parts : SS 304
Specific gravity	1	0.9 gm/cc *
Shell ing anticoms grilled Shell		5.0 mm thick SS 316 cylindrical with flange
Bottom log rould) ding 045 .s.		5.0 mm thick SS 316 conical dish end type welded with shell.
Тор	•	5 mm thick SS 316 Tori spherical dish end welded with flange.
Flange 193 (nogomoff br	8 1971	16 mm thick SS 316 -2 Nos. welded
Jacket	o type	4 mm thick SS 304 with spiral stiffeners
Gasket Gasket Gasket Gasket	99 (99)	Silicon gasket
ting type 3 Hos.	876 ( PS	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







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#### DESCRIPTION

( To be sp	ecif	fied by the supplier, if any variation)
Vessel Connections :	Hu	( To be specified by the s
Hand hole	:	150 mm dia with hinge type lid and silicon "O" ring
Light glass	158)	4" dia with flange
Sight glass	(5)	4" dia on hand hole Lid.
Vacuum Inlet (VI/VB/CG)	\ep	1 ½" dia TC end
CIP connection	231	2"x1" dia TC 1 no. with common header for spray ball
Product temperature	g <b>i</b> l	11/2" dia TC end at bottom of vessel deal orbyH
Product outlet	:	Flush bottom valve
Product temperature	:	1½" dia TC end *
Product outlet	:	Flush bottom valve*
Vessel Design parameters :	ujb	a-Nestor rotstipA
Working temperature	•	30 to 125 degree C.
Design Temperature	:	20 to 135 degree C. X58 1690
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 s	pecif	ied by the supplier, if any variation)
Jacket Design parameters :	AL SI	Hand hole : 150 mm c
Working temperature	si <b>i</b> r	35 to 135 degree C. *
Design Temperature 50 8 8 8 8	n:	25 to 150 degree C. *
Working pressure	•	3.5 to 4 kgs/cm sq. * 2018/40V) Isini muusav
Design pressure miles dilw an	•	4.0 to 4.5 kgs/cm sq. *
Hydro test pressure MONDO 15 0	19:0	5.5 to 6.0 kgs/cm sq. * shallongment bottom?
Jacket nozzles connections	7:0	For Steam inlet, cooling water outlet, pressure gauge etc 11/2"dia TC end
Miscellaneous details		1 Sign Let 1
Agitator	•	Anchor type semi-contra designed with Teflon scrappe and self-adjusted
Motor	osto	* HP /415 V/1440 rpm (FLP)
Gear Box	i	30:1 ratio engrapara regised
Shaft seal		Oil seal anuseing potshow
Vessel welding	kgg	Vessel is argon arc welded & smooths grinding finish from inside & outside.
Vessel Finish	(202)	Internally: 0.5 Ra. 240 grit (Mirror polish)  Externally: 0.8 Ra. 180 grit (Matt finish)
Accessories:	1 25	Isilique sits va minnos une ventorque se or
VFD		Anchor Stirrer and Homogenizer
Compounding gauge	:	Diaphragm type
Temperature sensor	:	TC end 0 to 250 degree C with class A accuracy 8 Transmitter



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		DESCRIPTION
(To be s	pecif	fied by the supplier, if any variation)
Spray ball	:	360 degree rotating type 3 Nos.Spray Tech make
Vessel Lamp	01 :	LED Lamp (FLP)
Sight Glass with Wiper	ei :	100 mm dia
Steam Inlet/ Condensate	ad har	Pneumatic actuated Valve with steam trap
CIP Inlet \$08 88 agriculture	1	Pneumatic actuated valve BFV
Lid lifting arrangement	1	Manual with davit Arm
SS 316 cylindrical with Flange PID CIP Content dish and welded	**************************************	CIP Drain & Utility header along with 1 Nos. Pneumatic actuated BFV valve.

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







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		DESCRIPTION ed by the supplier, if any variation)
4) Storage Vessel		
Capacity		Working: 100 to 120 liters ( 100 Kgs)  Gross: 150 to 160 liters *
tuated Valve with steam trap  20M tuated valve BFV		Contact parts : SS 316 CONTACT NON-contact parts : SS 304
Specific gravity	riživ	0.9 gm/cc *
Shell daw prois rebent value	8.01	5.0 mm thick SS 316 cylindrical with Flange
Bottom		5.0 mm thick SS 316 conical dish end welded with shell
per their equipment desirgoT		5.0 mm thick SS 316 Torispherical dish end type welded with the flange
Legs	:	4 Nos. SS 304 pipe legs.
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	1	5 micron SS sintered filter 1.5" dia TC end
	1	





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	DESCRIPTION
( To be sp	pecified by the supplier, if any variation)
Vessel Welding	: Vessel is argon arc welded & smooth grinding finish from inside & outside.
Vessel Finish	: Internally: 0.5 Ra. 210 grit (Mirror polish)  Externally: 0.5 Ra.210 grit (Mirror polish)

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MOTT	HIA:	DESCRIPTION
( To be spec	ified	by the supplier, if any variation)
WATER RING VACUUM PUMP		
Туре	us ž	Water ring
Motoralleg administration Motoralleg Microsoft	( cill	*HP/2800 RPM FLP/Foot Mounted *
Flow rate	1	50 cfm *
Ultimate Vacuum	:	710 mm of hg *
Water inlet flow required	5 19	7 liters per minute with pneumatic actuator valve and flow sensor auto operation.
Temperature	:	Ambient Temperature
CIP RE-CIRCULATION PUMP		
Capacity		200 liters CIP tank with pump
Pump	<b>!</b>	*HP/ FLP *
Flow rate	:	50 LPM*
Scope of supply	•	To clean vessels and pipe line with re-circulation & CIF drain with conductivity sensor, transmitter, valves 8 pipe line etc.
MANUFACTURING VESSEL TO	STOF	RAGE VESSEL PUMP
* Lobe Pump		
Capacity		Max 1000 Kgs per hour depending upon productiviscosity *
Motor	:	* HP, 960 RPM, 3 Phase, 415V * (FLP)
Construction		Aluminum Casting Body with powder coated. Interna Contact parts SS316 and non-contact parts SS304

\* 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)

#### STORAGE VESSEL TO FILLING HOPPER LINE

# Lobe Pump II religious entry de bellioses ed of )

·						
Capacity	20 65	Max 500 Kgs per hour depending upon product viscosity *				
Pump	:	* 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:

#### Interconnecting pipes

- > All internal connecting pipe line between manufacturing vessel, wax vessel, water vessel and transfer storage vessel with manual butterfly valve and with TC joints.
- > All pipes should be Electro polished and joints TC Connection

#### SS Working Platform:

Should be made out of SS 304 square pipe frame work with top SS 304 dimple sheet with ladder and railing. S.S railing is provided all three sides of the platform.

Legs: S.S round pipe legs are provided.

Complete S.S 304 platform GMP Standard.

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

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#### ANNEXURE - V : ELECTRICAL DETAILS

( To be specified		CRIPTION he supplier, if any variation)
Standard Operating Frequency	. n <b>.</b> siv	50 Hz
Standard Operating Voltage	isto:	230 / 415V*
Total power consumption	imul/	*
Motor Details with rpm	sino?	* Construction
Gear Box Details (If any)	ed due	◆ High & Low-level sensor* **
PLC and HMI details		The plant must include the following: *
VFD details (If any)		* interconnecting pipes *
Tower lamp	veen	All Internal connecting pipe line to
Starter		* The righton system 2 and blungly spate 116 - 4
Major Cabling details		SS Working Platform :
For Main supply (In client's scope)	ediq	Should be made out of SS 304 square
For Main drive motor and to sable assu	ld He	ladder and railing. S.S railing is provised
End connection details		MCB or Socket should be with equipment
Earthing requirement	:	Arrangement should be with system
An Isolator Circuit breaker	, b	To be supplied with machine at power supply in point of appropriate capacity by vendor. *
Cable length with equipment	llqqı	* To be specified and confirm by the si

Any other detail not mentioned above, also to be included.

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.

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



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fied by the supplier, if any variation)
as specified by the sa
: Should be made of SS 304 sheet with following:  • All contractor  • Relay  • MCB  • PLC /Analog inputs  • Output card  • VFD  • Modbus communication  • HMI cable from PLC to HMI for automation Pneumatic solenoid valve/ relay card etc.
44 Absezo Bi Ulitaria de Caracia
<ul> <li>Should be made of SS 304 sheet with following:</li> <li>Touch screen 10" IPC</li> <li>Emergency &amp; Key switch</li> <li>Auto/Manual function selection etc</li> </ul>

### 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

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



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# notished you to redique 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 - VI : SAFETY FEATURES

#### DESCRIPTION

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

#### **Interlock Control:**

- > 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 propoer , 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 - VII : UTILITY REQUIREMENT

(To be spe	cifie	ed by the supplier, if any variation)
Vacuum	i Abi	Interlock Control:  *  If vacuum pump is on hydraulic power pr
Compressed Air	7:01	Ordinary * 00 fill ni tebalic cylinsthyd II
	O H	If flow of cooling water in medianical se     Non-Lubricated *  Non-Lubricated *
Water	pins	> When steam valves are in operation, (a)
3.19 al establishment	b	s wild blooder should blow a
Chilled Water		If temperature over shoots, hooter sh
Nitrogen		The equipment should be provided with material *  In the event of equipment malfunction or st
Cooling water	ingi	necessary protection devices to ensure that each
power failure.		Equipment settings should not get disturbed du
Steam	100	Pure Steam* Live in stage for bloods anomquipa
isual signal with details on Cont		Equipment should indicate fault * meste was (Failure mode detection)
Any other lanse lorging its in no		An easily accessible emergency stop to be p.*.

\* 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 - VIII CLEANING TECHNIQUE

( To be specifie		CRIPTION the supplier, if any variation)
Mode of machine cleaning		*
Use of Lubricants	2 5 111	( Fo he specified by

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 - IX

MECHANICAL DETAILS

(To be specif	<b>DES</b>	SCRIPTION 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 - X : LIST OF ANCILLARY / ACCESSORIES / OPTIONAL

ITEMS TO ROUGH

#### DESCRIPTION

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

- Optional Items (If any , Vendor should provide the list with rate) \* 100 line
- 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

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





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#### ANNEXURE - XI : 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.





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



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### ANNEXURE - XII : APPROVED MAKES

Stainless Steel Sheet & Pipe: Tata / Jindal	:	and Cleaning of a*
Motor: Siemens / Bharat Bijlee / Hindustan / Bonfiglioli / Panasonic		provided by vendors
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		*

- Any other components, not mentioned above, to be specified by the vendor.
- 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.

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



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ANNEXURE - XIII

DOCUMENTATION

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	MSUBHADIN AND I
9	Warranty / Guarantee agniwarb Boa	2 sets	Submission of
10	List of all components with referencing	2 sets	Response to URS
11	Civil foundation drawings	2 sets	sh to negationing
12	Pre installation requirements	<del></del>	one moutefilledus
13	Installation requirements	2 sets	Not be anticonnective
14	Installation manual	2 sets	M to moiseimnis
15	Technical literature, data sheets and equipment catalogues	2 sets	Drestings / diagr
16	DQ, IQ, PQ documents.	2 sets	The supplier situ
17	Calibration Report of all sensors, controllers, PLC, transmitters, indicators etc.	2 sets	Catelogue, Equi
18	Test Certificates of all material of construction	2 sets	asiono iti wones
19	Test Certificates of the software used in machine control / monitoring system.	2 sets	



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#### **ANNEXURE - XIV TERMS AND CONDITIONS**

Delivery Period	:	*				
Payment Terms  Packaging and Forwarding  Un-loading at site		As mentioned in tender.  By Vendor  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	-:-	6 All engineering drawings
				Material for Trial arrangment		* (To be arranged by client)
Installation and Commissioning		By Vendor certification Value				
Submission of documents and drawings		9 Warranty / Guarantee				
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.

Any other terms, not mentioned above, also to be specified.

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



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#### ANNEXURE - XV

#### ABBREVIATION

1.	URS	:	User Requirement Specification.	
2.	номсо	:	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 XIV, to be specified in the quotation/specification by the vendor.



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