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Supplier's Copy

USER REQUIREMENT SPECIFICATION

	TOTA	2850
iet, if any variation)	50.05	(To be specified by the
Contact Person	GI A	Scope : Suppl
i se ste comment - CREAM Manufe all interconnecting piping, pum	THE REAL PROPERTY.	
Address Address	de cu	platio
ing with connecting accessories. Cal		
Contact Details	On .	Mu 16
n Manufacturing Hank (Steam heat	2922	marriage)
Department		Ointment - (Ground Floor)
Separement		labom
Equipment and Code No.	1001	Ointment /Cream Manufacturing Plant
to 125 litters *	120	Capacity (In litres) Net
Name of work / *21911 031 03		Supply, Installation, Commissioning 8
Name of work	Det:	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Crean
en 160 liters* - Now to small	oat saluar oV xs	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Crean
to 160 liters* - Now to emak cturing Vessel ssel lessel	i squ anufad ax Ve ater V	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Crean Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
turing Vessels ssel essel vessel be Puma (2 Nos)	tso ax Ve ater V orago	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Crean Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
to 160 liters* - Now to ameN cturing Vessel ssel essel	tod ax Ve ater V oragi vio Li ansfe	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Crean Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
turing Vessel seel essel vessel be Pump (2 Nos) Pump and Date	anutac ax Ve ax Ve ater V vin Lu anate acuun	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
turing Vessel ssel vessel vessel he Pume (2 Nos) neecting piping platform	sa Ve ax Ve ater V oraga analo analo te con	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Crean Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
to 160 liters turing Vessel ssel vessel be Pume (2 Nos) reump neecting piping platform panel	sa Ve ax Ve ater V oraga analo icuul te co ontro	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Cream Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala
Name of work turing Vessel essel essel essel essel Pump (2 Nos) Date Date Date Enclosures d on the capacity manager of the capacity manager	sa Ve ater V oraga anale scuut te cal ontro	Supply, Installation, Commissioning & Validation of cGMP model Ointment/Crean Manufacturing Plant – 100 KG at M/s. HOMCO-Kerala



CONSULTANT: M/S. KNACK TECHNOCRATS





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DINTMENT/CREAM MANUFACTURING PLANT - 100 KGS (STEAM HEATED)

ANNEXURE - I BASIC DETAILS OF THE MACHINE

(To be s	peci	DESCRIPTION ified by the supplier, if any variation)			
Scope :		 Supply, Installation, Commissioning & 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 			
		Ointment/Cream Manufacturing Plant (Steam heated plant)			
Model	:	Department : Oilune			
Туре	:	*			
Capacity (In litres)	:	Working: 100 kgs * Net : 120 to 125 liters * Gross : 150 to 160 liters*			
The Main plant Consist of	11.U	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 'O' ri		DESCRIPTION SIGNATURE
(To be sp	ecif	ied by the supplier, if any variation)
1) Manufacturing Vessel	gec	Sight glass 1 4° dia Flan
Capacity Dead nomino ddiw .eon		Working: 120 to 125 liters (100 Kgs) Gross: 150 to 160 liters *
MOC * on 1-	bne	Contact parts : SS 316 Pallimental Pauseens Non-contact parts : SS 304 Palson and 3
Specific gravity	d lo	0.9 gm/cc * * and some *
Shell * (daib to got nO) b	ng 0	5.0 mm thick SS 316 cylindrical with flange *
Bottom	ns 0	5.0 mm thick SS 316 conical dish end welded with shell*
genizer by Tee connection* qoT & Stator type. Skid mounted	orio lata	5 mm thick SS 316 Tori spherical dish end welded with flange *
Flanger and publication for 101 (9.		16 mm thick SS 316 -2 Nos. welded *
Jacket	18	4 mm thick SS 304 with spiral stiffeners*
Gasket	:	Food Grade Silicon Gasket*
Insulation	psio	50 mm thick mineral wool duly cladded with 14 SWG SS 304 sheet *
Legs pan	10/13	4 Nos. SS 304 pipe with base plate to suit load cell bracket*
Load cell *.pa mo		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

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



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лоятилЭ вварояЯ ВЗЯЦТ.		DESCRIPTION fied by the supplier, if any variation)
Vessel Connections :		
Hand hole	110	150 mm dia with hinge type lid and silicon 'O' ring*
Light glass (not be to your in the	g i	4" dia with flange*
Sight glass	:	4" dia Flange on hand hole Lid*
Vacuum Inlet	0 1 :	1 ½" dia TC end*
CIP connection * and light of	07 8 3	2x1" dia TC 1 nos. with common header for spray ball*
Pressure Transmitter	:	1½" dia TC *
Extra nozzle 408 28 - 25	q : 00	1" dia TC end -1 no. *
Anchor Stirrer	:	On center of top dish*
Product recirculation) 3 1	11/2" dia TC end (On top of dish) *
Product temperature	y : [1½" dia TC end *
Product outlet	2 : k	Through homogenizer by Tee connection*
S 316 -2 Nos. welder had been selfeners.	ck 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 :	18.9	Gasket : Food Grad
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	133	-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	specif	fied by the supplier, if any variation)
Jacket Design parameters :		Accessoriest
Working temperature	AE 39)	35 to 135 degree C. *
Design Temperature	i i	25 to 150 degree C. *
Working pressure	:	4 kgs/cm sq.Working. *
Design pressure	76 01 9	4.5 kgs/cm sq. *
Hydro test pressure	(-117)	5.5 to 6.0 kgs/cm sq. * 9m6.1 lesseV
Jacket nozzles connections	:0 5:108	For Steam inlet, cooling water outlet, pressure gauge etc. 1½"dia TC end
Miscellaneous details		miles recovered.
Agitator	51 158	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 sign attiw amed earneb -	0 =	*HP /415 V/TEFC 1440 rpm (HMM Make-FLP). *
Gear Box	_ :	30:1 ratio *
ted BFV or Assembly with Liclass flad? pack unit & PLF motor	Agil at	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 11 E	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 s	specif	fied by the supplier, if any variation)
Accessories:		
VFD		Anchor Stirrer and Homogenizer
Compounding gauge	:	Diaphragm type
Pressure sensor	i	1 to 5.0 kgs/cm sq.
Spray ball		360-degree rotating type
Vessel Lamp	2.63	LED Lamp (FLP)
Sight glass with Wiper		100 mm dia
Vacuum Inlet	bae	Pneumatic actuated BFV
Vacuum breaker with Filter	ŀ	Pneumatic actuated BFV
Steam inlet/Condensate		Pneumatic actuated Valve with steam trap
Cooling Inlet/ Outlet	nio y Sp.no	Pneumatic actuated Valve with jacket drain
Temperature sensor	Tiv	TC end 0 to 250 – degree temp with class 'A' accuracy 8 Transmitter
CIP Inlet dsal/ds3 - (H) lass	s puis	Pneumatic actuated BFV
Hydraulic lifting arrangement	u n.ši	To lift top Agitator Assembly with Lid 500mm ht. including Hydraulic Power pack unit & FLP motor.
Load cell 4 Nos.	N Die	For vessel legs with junction box & FLP digital weights indicator with 0.05% accuracy least count 500gms in total volume
Ra, 240 grit Mirror politish bisk?	H.G.	S.S 304
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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	ecif	DESCRIPTION ied by the supplier, if any variation)
2) WAX Vessel		Con to an or y
Capacity	19,0	Working: 50 to 60 liters (50 Kgs) Gross : 75 to 85 liters
MOC	r s o	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	090	4.0 mm thick SS 316 Elliptical dish end welded with shell
Тор	ola L	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 pe ma	KGBX	4 mm thick SS 304 with spiral stiffeners
Gasket	:	Food Grade Silicon Gasket 199 ngies@ 1990at
Insulation	det	50 mm thick mineral wool duly cladded with 14 SWG SS 304 sheet
Legs	190	4 Nos. SS 304 pipe with base plate to suit load cell bracket
Vessel Connections:	98/1	Working pressure t 3.5 to 4 k
Hand hole	9.	150 mm dia with hinge type lid and silicon 'O' ring
Light glass	o.i.	4" dia with flange
Sight glass	:	4" dia on hand hole Lid.
Vacuum Inlet/VB/CG	:	1 1/2" dia TC end Sonnections 3/2" dia TC end
CIP connection	:	2"x1" dia TC 1 Nos. with common header for spray ball
Anchor Stirrer	95	On center of the top dish as belilbage ad of *

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



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	oecif	DESCRIPTION ied by the supplier, if any variation	ion)
Vessel Connections :	e re	indohniy i s	7. 7. 7. 7. 7. 7. 7. 7. 7. 7. 7. 7. 7. 7
Product temperature	1.5	1½" dia TC end	Capacity
Product outlet	2 115	Flush bottom valve	SOM
Vessel Design parameters :	g Joi	Non-conti	
Working temperature		30 to 125 degree C.	Specific gravity
Design Temperature	N.Ser	20 to 135 degree C.	Gotton
Working pressure	≥ 1 0	-1 to 2 kgs/cm sq.	net
Design pressure	•	-1 to 2.25 kgs/cm sq.	
Hydro test pressure	2 1	-1 to 3.0 kgs/cm sq.	ogaen texasi
Jacket Design parameters :	18 81	Food Grace	Gasket
Working temperature	1:	35 to 135 degree C. *	goitsluarii
Design Temperature	ı	25 to 150 degree C. *	250.1
Working pressure		3.5 to 4 kgs/cm sq. *	Vessel Connec
Design pressure	•	4.0 to 4.5 kgs/cm sq. *	Hand hole
Hydro test pressure	ll e	5.5 to 6.0 kgs/cm sq. *	Light glass
Jacket nozzles connections has		For Steam inlet, cooling water 11/2" dia TC end	outlet, pressure gauge etc

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NO		DESCRIPTION
		ied by the supplier, if any variation)
Miscellaneous details	T ()	· anishaW ·
Agitator # anglif 0at of.	në r	Anchor type semi-contra designed with Teflon scrapper and self-adjusted
Motor are 22 :	aint	
Gear Box 408 22 : 246	q io	30:1 ratio
Shaft seal	· ·	Specific gravity
Vessel Welding Sambrilly of E. 22	si s ir	Vessel is argon arc welded & smooths grinding finish from inside & outside.
Vessel Finish	i i	Internally: 0.5 Ra. 240 grit (Mirror polish) Externally: 0.8 Ra. 180 grit (Matt finish)
Accessories:	פוג א	Top. 1 5 mm this
SS 316 -2 Nos. welded	ick)	Anchor Stirrer and Homogenizer
Compounding gauge	ık sı	Diaphragm type
Temperature sensor	n is	0 to 250 degree C with class A accuracy & Transmitter
Spray ball bab you look terenim	яŝі	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

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



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		DESCRIPTION
		ied by the supplier, if any variation)
3) Water Vessel		(To be specified by the s
Capacity _w bengiseb stinon-line, bed	2015	Working: 120 to 125 liters (100 Kgs) Gross: 150 to 160 liters *
440 rpm DOM	1\1	Contact parts : SS 316 Non-contact parts : SS 304
Specific gravity	:	0.9 gm/cc *
Shell be smooths grilled	og 16	5.0 mm thick SS 316 cylindrical with flange
Ra. 240 grit (Mirror goll mottod	i.i.	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 1931nagomoH bng	ime	16 mm thick SS 316 -2 Nos. welded
Jacket	g),a	4 mm thick SS 304 with spiral stiffeners
Gasket Saudos A 2265 diw 3 es	legal	Silicon gasket
nation type 3 Nos.	1 94	50 mm thick mineral wool duly cladded with 14 SWG SS 304 sheet
Legs	:	4 Nos. SS 304 pipe with base plate

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DESCRIPTION

		DESCRIPTION
(To be spe	ecif	ied by the supplier, if any variation)
Vessel Connections :		(To be specified by the
Hand hole	:	150 mm dia with hinge type lid and silicon "O" ring
Light glass	91)	4" dia with flange enutereques gashow
Sight glass	31 0	4" dia on hand hole Lid. emperagmet npReG
Vacuum Inlet (VI/VB/CG)	\ e p	1 ½" dia TC end
CIP connection • pe mo\	2	2"x1" dia TC 1 no. with common header for spray ball
Product temperature * ,pe mp/p	g ė l	11/2" dia TC end at bottom of vessel deed onby H
Product outlet	ri (Flush bottom valve
Product temperature		1½" dia TC end *
Product outlet		Flush bottom valve*
Vessel Design parameters :	ulta	Agitator and self-s
Working temperature mg 044	Y	30 to 125 degree C.
Design Temperature	:	20 to 135 degree C. XSS 1890
Working pressure	:	-1 to 2 kgs/cm sq.
Design pressure	OTE STU	-1 to 2.25 kgs/cm sq.
Hydro test pressure	4	-1 to 3.0 kgs/cm sq.

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		DESCRIPTION
(To be s	pecif	fied by the supplier, if any variation)
Jacket Design parameters :	W, 611	. Hand hole : 150 mm d
Working temperature	51 : f	35 to 135 degree C. *
Design Temperature	A:0	25 to 150 degree C. *
Working pressure	•	3.5 to 4 kgs/cm sq. * 20\8V4V) Joint muubeV
Design pressure	•	4.0 to 4.5 kgs/cm sq. *
Hydro test pressure months to	18:0	5.5 to 6.0 kgs/cm sq. * Stuffs squared butters
Jacket nozzles connections	100	For Steam inlet, cooling water outlet, pressure gauge etc. 11/2"dia TC end
Miscellaneous details		
Agitator	1	Anchor type semi-contra designed with Teflon scrapper and self-adjusted
Motor	050	* HP /415 V/1440 rpm (FLP)
Gear Box	<u>i</u> b	30:1 ratio engerature oits 1:08
Shaft seal	ŀ	Oil seal equision problem
Vessel welding	K.G.	Vessel is argon arc welded & smooths grinding finish from inside & outside.
Vessel Finish	(SB)	
Accessories:		Externally: 0.8 Ra. 180 grit (Matt finish)
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
(nobshay v (To be sp	pecit	fied by the supplier, if any variation)
Spray ball		360 degree rotating type 3 Nos.Spray Tech make
Vessel Lamp	oi:	LED Lamp (FLP)
Sight Glass with Wiper	. i	100 mm dia
Steam Inlet/ Condensate	e i e	Pneumatic actuated Valve with steam trap
CIP Inlet 408 88 1 amso	\$15	Pneumatic actuated valve BFV
Lid lifting arrangement	1	Manual with davit Arm
SS 316 cylinddeal with Flange PID s SS 316 conteal 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 ecified by the supplier, if any variation)
4) Storage Vessel	Spray ball : 360 degree i
Capacity .	: Working: 100 to 120 liters (100 Kgs) : Gross: 150 to 160 liters *
tuated Valve with steam trap DOM tuated valve BFV	Contact parts : 33 310
Specific gravity	: 0.9 gm/cc * management point bill
Shell dilw paole rebeet villeu	: 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 designor	: 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	: 5 micron SS sintered filter 1.5" dia TC end



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	DESCRIPTION
(To be sp	ecified 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)

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





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		DESCRIPTION by the supplier, if any variation)
WATER RING VACUUM PUMP		Vessel Welding
Type		Water ring
L.S. Ra. 210 gelt (Mirror polis rotoM	2:11	*HP/2800 RPM FLP/Foot Mounted *
Flow rate	- 3:10	50 cfm *
Ultimate Vacuum	:	710 mm of hg *
Water inlet flow required	135	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	:	*HP/ 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	STO	RAGE VESSEL PUMP
* Lobe Pump		
Capacity	•	Max 1000 Kgs per hour depending upon product viscosity *
Motor	:	* HP, 960 RPM, 3 Phase, 415V * (FLP)
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



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DESCRIPTION

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

STORAGE VESSEL TO FILLING HOPPER LINE

Lobe Pump

Capacity	1 63	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 specifie		CRIPTION he supplier, if any variation)
Standard Operating Frequency	, x 5 16	50 Hz
Standard Operating Voltage	viscos	230 / 415V*
Total power consumption	emida	*
Motor Details with rpm	sino?	Construction
Gear Box Details (If any)	otduc	◆ High & Low-level sensor,
PLC and HMI details		The plant must include the following: *
VFD details (If any)		* Interconnecting pipes
Tower lamp	neen	All internal connecting pipe line by
Starter		* hedgles extend ad bluods sociality -
Major Cabling details		SS Worldon Platform
For Main supply (In client's scope)	polo	Should be made out of SS 304 square
For Main drive motor	dd lla	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	allqqu	* To be specified and confirm by the

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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		DESCRIPTION
(To be spe	cifie	d by the supplier, if any variation)
Power Panel : (FLP)	QUE	(To be specified by the
	:	Should be made of SS 304 sheet with following:
	le s	Mining between rotation of the child
e site.	17 8	the • v Relay od llade alnomeruseem
	Hei	MCB M
Scope 1 31 be five id and finds are		DIC /Apples inputs
Scope		Output card
	1 93	• VFD Isself on the State Office of VFD
	Aff	Modbus communication
		 HMI cable from PLC to HMI for automation Pneumatic solenoid valve/ relay card etc.
Remote Panel :		
	:	Should be made of SS 304 sheet with following :
		Touch screen 10" IPC
Scope and Policina on the same	2 111	Emergency & Key switch
		Auto/Manual function selection etc
SCADA SYSTEM: SCADA softwa 4 GB RAM with USB port, key pa		vith 2000 Tags lab view /Dell make PC with 1 TB hard disl

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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nother war if any variation

(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

(noiteney vote in 1976) (To be spec	cifie	DESCRIPTION d by the supplier, if any variation)
Vacuum	ΑDI	Interlock Control: * If vacuum pump is on hydraulic power pa
Compressed Air issins gonord bas started in a started off		Ordinary * 00 #il ni rebnilyo piliushbyn #I < less isolnishem ni retikw gniloop to wpit #I Non-Lubricated * notikwa wofi nguomit
Water Motaling and Marketin PLC		When steam valves are in operation, cut A if air pressure low ,hooter should blow a
Chilled Water Sylav Islan bits wo	•	If temperature over shoots, hooter shots
Nitrogen		In the event of equipment malfunction or su
Cooling water		necessary protection devices to ensure that extending the settings should not get disturbed du
Steam	•	Pure Steam* The Instant son bloods anomquip
visual signal with details on Cont		Equipment should indicate fault * maste was (Failure mode detection)
Any other lanes longers aliem as I	:	An easily accessible emergency stop to be pi*v

* 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

	DES	SCRIPTION
(To be spec	cified by	the supplier, if any variation)
Mode of machine cleaning		*
Use of Lubricants	qqua sins	(To be 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	DES	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 COL

DESCRIPTION

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

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

(ap) Int (gs)

A Grade

A Grad

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 John John John John John John John John	•	and Cleaning of al*i
Motor: Siemens / Bharat Bijlee / Hindustan / Bonfiglioli / Panasonic	i ir	provided by vendox
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	Las nonsiblem
9	Warranty / Guarantee agmiws to bus	2 sets	Submission of
10	List of all components with referencing	2 sets	Response to URS
11	Civil foundation drawings	2 sets	Submission of da
12	Pre installation requirements		one mortesitioner
13	Installation requirements	2 sets	3 in anisatesta?
14	Installation manual	2 sets	M to observance
15	Technical literature, data sheets and equipment catalogues	2 sets	Drewings / dragn
16	DQ, IQ, PQ documents.	2 sets	The supplier sing
17 MJU2	Calibration Report of all sensors, controllers, PLC, transmitters, indicators etc.	2 sets	Catalogue, Equi
18	Test Certificates of all material of construction	2 sets	
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 HADLISTA ZA Hashigiupa dii		As mentioned in tender.	
Packaging and Forwarding	ulia s	By Vendor and	
Un-loading at site		By vendor /Supplier	
		(If required, help for the arrangemen of unloading can be done by client)	
		Installation in position by the vendo under the client's supervision	
Excise / Taxes /GST	1	6 All engineering drawings	
Material for Trial arrangment		* (To be arranged by client)	
Installation and Commissioning		By Vendor certification 8	
Submission of documents and drawings		9 Warranty / Guarantee	
Response to URS and submission of quotation		Within 1 week mos lis to Jal. O.	
Submission of detail functional design		Within a week after order finalization	
specification and schematic drawings		12 Pre-installation requirements	
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.	0&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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