

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT

PROTOCOL No.:

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT

EQUIPMENT ID. No.	
LOCATION	Manufacturing Line
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



PROTOCOL No.:

MULTI MIX MANUFACTURING PLANT

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MULTI MIX MANUFACTURING PLANT

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1.0 PROTOCOL PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD			
(QUALITY ASSURANCE)			



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2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Multi-mix manufacturing plant and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this Operational Qualification Protocol Cum Report is limited to perform operational qualification of Multi-mix manufacturing plant (Make: Bectochem Consultants & Engineers Pvt. Ltd.) installed in Manufacturing line.
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity of Multi-mix manufacturing plant.
- Successful completion of this Protocol Cum Report will verify that equipment meets all acceptance criteria and ready for Performance Qualification.



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4.0 **RESPONSIBILITY:**

The Validation Group, comprising of a representative from each of the following departments shall be responsible for the overall compliance of this Protocol Cum Report:

DEPARTMENTS	RESPONSIBILITIES	
Quality Assurance	 Preparation, Review, and Approval of the operational Qualification Protocol Cum Report. Co-ordination with Production and Engineering to carryout Operational Qualification activity. To compile all the data generated during operational qualification activity. Monitoring of Operation Process Post Approval of Operational Qualification Protocol cum Report after 	
Production	 Execution. Review of Operational Qualification Protocol cum Report. To execute the operational qualification activity in co-ordination with QA and Engineering. To provide necessary material (if any) during the operational 	
Engineering	 qualification activity. Pre-approval of Operational Qualification Protocol cum Report. To co-ordinate and support Operational Qualification Activity. To provide necessary utilities required during operation of equipment. Post Approval review of Operational Qualification Protocol cum Report after Execution. 	



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5.0 EQUIPMENT DETAILS:

Equipment Name	Multi-mix Manufacturing Plant		
ID. Number			
	Type of vessel	Working Capacity	Gross Capacity
	Wax Phase Vessel	30 Liters	40 Liters
Capacity	Water Phase Vessel	30 Liters	40 Liters
	Main Manufacturing Vessel	60 Liters	75 Liters
	Storage Vessel 60 Liter		75 Liters
Manufacturer's Name	Bectochem Consultants & Engineers Pvt. Ltd.		
Supplier's Name	Bectochem Consultants & Engineers Pvt. Ltd.		
Location of Installation	Manufacturing Line		

Checked By	Verified By
Engineering	Quality Assurance
Sign/Date:	Sign/Date:



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6.0 EQUIPEMENT DESCRIPTION:

The Multi Mix Manufacturing Plant is designed to process pharmaceutical products i.e. Multi mix / cream / gels / lotion in accordance with cGMP principles. The Multi mix manufacturing plant is comprises with following equipments;

- 1. Wax (Oil) phase Vessel
- 2. Water (Aqueous) Phase Vessel
- 3. Main Manufacturing and Mixing Vessel
- 4. Vacuum Pump (Water Ring Type)
- 5. Twin Lobe Transfer Pump
- 6. Storage Tank
- 7. Product Pipeline
- 8. Centralized Electric Control Panel for entire process plant
- 9. In-Line Homogenizer

Wax (Oil) phase Vessel:

It is fitted with bottom mounted stirrer coupled to SS 316 shaft with agitator, pressure gauge, vent valve, safety valve rupture disc, and a temperature sensor with digital display. It is provided with bottom outlet connected to manufacturing vessel through a conical filter having SS mesh screen of 100# filter of melted waxes. It is also provided with the steam supply to the jacket.

Main Manufacturing and Mixing Vessel:

It consists of cylindrical shell and jacketed vessel. It is fitted with the top mounted SS 316 shaft with anchor having baffles and Teflon scrappers moving in a clockwise direction. One more baffles system is mounted in the inner side of the vessel. The vessel is provided with pressure release vent, safety valve rupture disc, gauge and a temperature sensor with digital display. The vessel is provided with bottom homogenizer and unloading of finished product to storage vessel using lobe pump. The vessel is also provided with steam and cooling water to the jacketed tank. The vessel is also provided with light glass, sight glass, charge hole and hand hold on top dished end. High speed homogenizer is installed at the manufacturing vessel.

Utility system:

A utility pendant is provided to bring the utility lines from the service floor to the platform so as to run the utility line below the platform.



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7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

Prior to start operational qualification activity, verify the below mentioned documents for their availability and record the same as per below table. Any deviations or issues if observed should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	AVAILABLE/NOT AVAILABLE	VERIFIED BY (QA) SIGN/DATE
1.	Executed and approved Design Qualification protocol cum report		
2.	Executed and approved Installation Qualification protocol cum report		
3.	Draft SOP for Operation & Cleaning of manufacturing vessel		
4.	Draft SOP for Preventive Maintenance of manufacturing vessel		

Inference:	
	Reviewed By
	Manager QA
	Sign/Date:



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7.2 **Test / Measuring Equipment Calibration:**

Prior to start operational qualification activity, verify the calibration status of instruments of multimix manufacturing plant as per below table. Any deviations or issues if observed should be rectified and documented prior to OQ commencing.

S.No.	INSTRUMENT NAME	INSTRUMENT I.D.	CALIBRATION DONE DATE	CALIBRATION DUE DATE	OBSERVED BY SIGN/DATE			
Produ	ked By Iction Date:			Verified By Quality Assurance Sign/Date:				
Infere	ence:							
•••••								
				Reviewed By Manager QA				
				Sign/Date:	• • • • • • • • • • • • • • • • • • • •			



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- **8.0** CRITICAL VARIABLES TO BE MET:
- 8.1 OPERATIONAL AND FUNCTIONAL CHECKS:
- 8.1.1 WAX (OIL) PHASE VESSEL:

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
1.	Main Power Supply	Connect the main power supply to the master panel of the machine. Turn ON the M.C.B switch available in control panel. Then switch ON the main switch.	Indicators of R-Phase, Y-Phase and B-Phase should glow.		
		Switch ON the PLC/HMI MCB switch	Display with company name		
		Switch ON the MCB-6	Wax phase vessel VFD should get activated		
2.	Agitator speed control	Set the agitator RPM to Minimum	The difference in between set RPM and observed RPM should be greater or less than 5 %.	Minimum RPM Optimum RPM Maximum RPM	
3.	Temperature control	Set the process temperature at three different set points and check the functioning of Solenoid valve operation.	Once the temperature reaches to set temperature, the solenoid valve at jacket inlet closes.	SET Temperature: Valve Open/Close: SET Temperature: Valve Open/Close: SET Temperature: Valve Open/Close:	
4.	Process Timer	Set 3 different times in control panel and verify the Start / Stop operation of Anchor	The anchor agitator operation start / stop time should match	SET Time : Real time: Paddle Agitator Start	



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S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)	
		Agitator against the stop	with time	Time:	Ź	
		watch in real time.	measured with	AM/PM		
			stop watch.	Paddle Agitator Stop		
				Time:		
				AM/PM		
				Actual run Time:		
				Min		
5.	Functionin	Set the RPM of	After set process			
	g of motor	agitator and process	time is over,			
	and	time Turn "ON"	motor will be			
	actuated	the actuated valve at	OFF and actuated			
	valve	jacket inlet to attain	valve will be			
		settable temperature.	closed.			
6.	HMI	Check the operation of	All the keys			
	Operation	the HMI screen on	should operate as			
		various parameters.	per specification.			
			Screen pad should			
			be readable			
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Reviewed By Manager QA Sign/Date:						



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8.1.2 WATER PHASE VESSEL:

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
1.	Water phase	Switch ON the MCB-5	Water phase		
	vessel: Main		vessel VFD		
	Power		should get		
			activated		
2.	Agitator	Set the agitator RPM to	The difference in	Minimum	
	speed control	Minimum,	between set	RPM	
		Optimum, &	RPM and	Optimum	
		Maximum	observed RPM	RPM	
		Measure the agitator	should be greater	Maximum	
		RPM with the help of	or less than 5 %.	RPM	
		Tachometer			
3.	Temperature	Set the process	Once the	SET Temperature:	
	control	temperature at three	temperature	Valve	
		different set points and	reaches to set	Open/Close:	
		check the functioning of	temperature, the	SET	
		Solenoid valve	solenoid valve at	Temperature: Valve	
		operation.	jacket inlet	Open/Close:	
			closes.	SET	
				Temperature: Valve Open/Close:	
4.	Process	Set 3 different times in	The anchor		
	Timer	control panel and verify	agitator	SET Time :	
		the Start / Stop	operation start /	Real time: Paddle Agitator Start	
		operation of Anchor	stop time should	Time: AM/PM	
		Agitator against the stop	match with time	Paddle Agitator Stop	
		watch in real time.	measured with	Time: AM/PM	
			stop watch.	Actual run Time:	
				Min	



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		ACCEPTANCE	OBSERVATION	OBSERVED BY
	TESTING	CRITERIA		(PRODUCTION)
				(SIGN/DATE)
Functioning of motor and actuated valve	Set the RPM of agitator and process time Turn "ON" the actuated valve at jacket inlet to attain settable temperature.	After set process time is over, motor will be OFF and actuated valve will be closed.		
HMI Operation	Check the operation of the HMI screen on various parameters.	All the keys should operate as per specification. Screen pad should be readable		
]	of motor and actuated valve	actuated agitator and process time Turn "ON" the actuated valve at jacket inlet to attain settable temperature. HMI Check the operation of Operation the HMI screen on	agitator and process time is over, motor will be the actuated valve at jacket inlet to attain settable temperature. HMI Check the operation of Operation the HMI screen on various parameters. Check the operation of Screen pad should be	of motor and agitator and process time is over, motor will be valve the actuated valve at jacket inlet to attain settable temperature. HMI Check the operation of the HMI screen on various parameters. Creen pad should be

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	Reviewed By Manager QA Sign/Date:



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8.1.3 MAIN MIXER:

S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION) (SIGN/DATE)
1.	Main Mixer: Main Power	Switch ON the MCB	Main Mixer VFD should get activated		
2.	ON/ OFF of the Anchor	Switch ON the Anchor	Agitator should get started		
2.		Switch OFF the Anchor	Agitator should get stopped		
	ON/ OFF of the cowl	Switch ON the cowl	Cowl should get started		
3.		Switch OFF the cowl	Cowl should get stopped		
4.	ON/ OFF of the Homogenizer	Switch ON the anchor of homogenizer	Homogenizer should get started		
4.		Switch OFF the anchor of homogenizer	Homogenizer should get stopped		
5.	Emergency	Run the mixer and press the emergency stop in between the process	The machine should get stopped immediately		



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S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	(PRODUCTION)
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6.	Agitator	Set the Anchor RPM to	The difference in	Minimum	
	speed control	Minimum,	between set	RPM	
		Optimum, &	RPM and	Optimum	
		Maximum	observed RPM	RPM	
		Measure the RPM with	should be within	Maximum	
		the help of Tachometer	± 2 RPM	RPM	
		Set the Cowl RPM to	The difference in	Minimum	
		Minimum,	between set	RPM	
		Optimum, &	RPM and	Optimum	
		Maximum	observed RPM	RPM	
		Measure the RPM with	should be within	Maximum	
		the help of Tachometer	± 2 RPM	RPM	
		Set the Homogenizer	The difference in	Minimum	
		RPM to	between set	RPM	
		Minimum,	RPM and	Optimum	
		Optimum, &	observed RPM	RPM	
		Maximum	should be within	Maximum	
		Measure the RPM with	± 2 RPM	RPM	
		the help of Tachometer			
7.	Temperature	Set the process	Once the	SET	
	control	temperature at three	temperature	Temperature: Valve	
		different set points and	reaches to set	Open/Close:	
		check the functioning of	temperature, the	SET	
		Solenoid valve	solenoid valve at	Temperature:	
		operation.	jacket inlet	Valve	
			closes.	Open/Close:	
				SET	
				Temperature: Valve	
				Open/Close:	
8.	Process	Set 3 different times in	The anchor		



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S.No.	TEST	METHOD OF TESTING	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (PRODUCTION)
		IESTING	CRITERIA		(SIGN/DATE)
	Timer	control panel and verify	agitator	SET Time :	
		the Start / Stop	operation start /	Real time:	
		operation of Anchor	stop time should	Anchor Agitator	
		Agitator against the stop	match with time	Start Time:	
		watch in real time.	measured with	AM/PM	
			stop watch.	Anchor Agitator	
				Stop Time:	
				AM/PM	
				Actual run Time:	
				Min	
9.	Lifting /	Lift the bowl by	The top lid		
	Lowering	pressing UP button	should go up and		
	Operation	when all the agitator	reach the		
		operations are on stop.	topmost limit		
			and then stops.		
		Press the Down button	The top lid		
		when all the agitator	should come		
		operations are on stop.	down touching		
			the bottom limit		
			and stops		
10.	Functioning	Set the RPM of	After set process		
	of motor and	agitator and process	time is over,		
	actuated	time Turn "ON"	motor will be		
	valve	the actuated valve at	OFF and		
		jacket inlet to attain	actuated valve		
		settable temperature.	will be closed.		
11.	HMI	Check the operation of	All the keys		
	Operation	the HMI screen on	should operate as		
		various parameters.	per specification.		
			Screen pad		
			should be		



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8.2	EQUIPMENT	VOLUMETRIC CAPA	ACITY (IN LITERS) TEST:

Wax (Oil) Pha	ase Vessel		Working Capacity: 40 Liters		
·	The objective of this test is to o	demonstrat	e that Vessel Capacity	provided is as agreed with	
Objective	the Equipment supplier and me				
Equipment	Process Water: Calibrated Ves	sel / equipr	nent to measure requir	red quantity for charging	
/ Instrument Used	water.		_		
	Charge 40 liters of Process W	ater using	calibrated cylinder/ ve	essel. Witness the quantity of	
Method	Water received by the vesse	el without	overflowing. Operate	e the equipment at process	
Applied	parameters as per SOP on oper	ration & cl	eaning of manufacturi	ing vessel. Three consecutive	
	trials must be tested as describe	ed before, i	in order to demonstrate	e Consistent performance.	
Acceptance	The water should be filled wi	ithout any	overflow in vessel ar	nd equipment should operate	
Criteria	without any abnormality.				
	Trial-I		Trial-II	Trial-III	
Observation					
Complies /					
Does not					
complies					
Checked By				fied By	
Production Sign/Date:				lity Assurance /Date:	
Inference:					
			Dovi	ewed By	
				ager QA	
			Sign	/Date:	



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Water Phase	Vessel		Working Capac	city: 40 Liters				
Objective	The objective of this test is to o	demonstrate tha	t Vessel Capacity	provided is as agreed with				
	the Equipment supplier and meeting User Requirement.							
Equipment / Instrument	Process Water: Calibrated Ves	sel / equipment	to measure requir	red quantity for charging				
Used	water.							
	Charge 40 liters of Process W	ater using calib	orated cylinder/ ve	essel. Witness the quantity of				
Method	Water received by the vesse		• •					
Applied	parameters as per SOP. Three		als must be tested	as described before, in order				
	to demonstrate Consistent performance The water should be filled with		flow in vessel ar	ad aguinment should energte				
Acceptance Criteria	without any abnormality.	unout any over	now in vesser ar	id equipment should operate				
	Trial-I	Tr	ial-II	Trial-III				
	111ai-1	11	141-11	111ai-111				
Observation								
Complies / Does not								
complies								
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Main Manufa	cturing Vessel		Working Ca	pacity: 60 Liters									
01: "	The objective of this test is to o	demonstrate that V	essel Capacity	provided is as agreed with									
Objective	the Equipment supplier and me	harge 60 liters of Process Water using calibrated cylinder/ vessel. Witness the quantity of later received by the vessel without overflowing. Operate the equipment at process rameters as per SOP on operation & cleaning of manufacturing vessel. Three consecutive later also must be tested as described before, in order to demonstrate Consistent performance. He water should be filled without any overflow in vessel and equipment should operate thout any abnormality. Trial-II Trial-III Verified By Quality Assurance											
Equipment	Process Water: Calibrated Vess	sel / equipment to	measure requir	red quantity for charging									
/ Instrument Used	water.												
	Charge 60 liters of Process Wa	ater using calibrate	ed cylinder/ ve	essel. Witness the quantity of									
Method	Water received by the vesse	el without overflo	wing. Operate	e the equipment at process									
Applied	parameters as per SOP on open	ration & cleaning	of manufacturi	ng vessel. Three consecutive									
	trials must be tested as describe	ed before, in order	to demonstrate	e Consistent performance.									
Acceptance	The water should be filled wi	ithout any overflo	w in vessel ar	nd equipment should operate									
Criteria	without any abnormality.												
	Trial-I	Trial-	II	Trial-III									
Observation													
Observation													
Complies /													
Does not complies													
Checked By			Veri	fied Rv									
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			Sign	/Date:									



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8.3 JACKET PRESSURE TEST

Objective	The object	inative of 41	his tost is to	ahaalz th	o procesure s	of the iceles	+		
Objective	The obj	ective of the	ms test is to	check th	e pressure o	л ше јаске	ι.		
	• Clo	ose the outl	let and drain	n nozzles	of jacket. F	ill the jack	et with w	ater.	
	• Clo	ose all nozz	zles to jacke	et (Inlet).	Pressurize j	acket using	g the pun	np to desired	pressure
		4.5 kg/cm x phase ver		manufactı	uring vessel	, 6.0 kg/cm	n ² for wat	er phase ves	sel and
		-		eloped us	sing calibrat	ted Pressure	e Gauge.		
Procedure		-			our with tim	ne interval o	of every	10 minutes a	and check
		-	lrop in the g						
		•						riation Repor	
		-	_		_			ssure as mer	
		_		-	_	_	essel is 3	$.0 \ kg/cm^2$, V	Vater
	pho	ase vessel d	and wax ph	ase vessei	l is 4.0 kg/c	m^2 .			
Acceptance Criteria	No pres	ssure drop	should be o	bserved f	For 30 Minu	tes.			
		n Mixing	1		ter Phase V	1		ax Phase Vo	
	Time	Pressure as shown on gauge	Pressure Drop	Time	Pressure as shown on gauge	Pressure Drop	Time	Pressure as shown on gauge	Pressure Drop
Observation									
Complies / Does not									



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8.4	V A	CU	UIVI	TEST

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Objective	The obj	jective of th	nis test is to	perform	the vacuum	test.			
Procedure	Value V	ce it has acl	e tank. Man hieved the and Checa able below	rk the vacu steady sta k for the d	te. rop if any o	over a perio	od of half	ed Vacuum g an hour. Rec be noted on	cord the
Acceptance Criteria	No Vac	cuum drop	should be o	observed f	or 30 Minu	tes.			
	Mai	in Mixing \	Vessel	Wat	er Phase V	essel	W	ax Phase Ve	essel
	Time	Vacuum as shown on gauge	Vacuum Drop	Time	Vacuum as shown on gauge	Vacuum Drop	Time	Vacuum as shown on gauge	Vacuum Drop
Observation									
Complies / Does not complies									
Checked By Production Sign/Date:						Qι	erified By nality As gn/Date:		
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8.5 LOAD TRIAL FOR MIXER

o.s LUAD	TRIAL FOR WITA												
Objective	To verify Performa	nce of agitator or	full load mixer.										
	• Fill the vessels	with water as pe	r their working cap	acity & th	nen turn th	e main su	pply						
	ON, press start	button.											
Procedure	Operate agitate	or for one hour.											
	Monitor the cu	rrent drawn by m	otor, Sound, Vibra	tion, over	heating of	the comp	onents						
	and document	in observation tal	ole.										
	The ampere re-	ading should not	exceed the rated Aı	np of mo	tor.								
Acceptance	Sound must no	ot exceed 80 dB a	t 1 meters linear dis	stance.									
Criteria	Temperature s.	hall be recorded f	for information.										
		ľ	Main Mixing Vesso										
	Description	Noise Level	Temperature		nt (Rated (2.5 Amper		RPM						
			r	R	Y	В							
	Motor			_									
_	Gearbox Regring Housing												
	Bearing Housing Mechanical Seal												
	Homogenizer												
	Description				nt (Rated C	D.D. 4							
	Description	Noise Level	evel Temperature		3.1 Amper Y	B	RPM						
Observation	Motor												
	Water Phase Vessel												
	Description				nt (Rated (1.1 Amper		200						
	Description	Noise Level	Temperature	R	Y	В	RPM						
	Motor												
		1	Wax Phase Vessel				1						
	Description	Noise Level	Temperature		nt (Rated (1.1 Amper		RPM						
	•	Noise Level	remperature	R	Y	В	KINI						
	Motor												
Complies / Does not complies													



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Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	Reviewed By Manager QA Sign/Date:



PROTOCOL No.:

MULTI MIX MANUFACTURING PLANT

8.6 INTERLOCK AND ALARM VERIFICATION

S.No.	TEST ACCEPTANCE CRITERIA		OBSERVATION	OBSERVED BY
				(ENGINEERING) (SIGN/DATE)
1.	Interlock of anchor motor with Lid position	The anchor motor should not start if lid is open		
2.	Emergency stop fault	The plant should get stopped on pressing the emergency press.		
3.	Anchor motor FB fault	The anchor motor FB fault alarm should be displayed as specified		
4.	Anchor motor trip	The Anchor motor trip alarm should be displayed as specified		
5.	Water phase motor FB fault	The water phase motor FB fault alarm should be displayed as specified		
6.	Water phase motor trip	The Water phase motor trip alarm should be displayed as specified		
7.	Power pack motor FB fault	The power pack motor FB fault alarm should be displayed as specified		
8.	Power pack motor trip	The power pack motor trip alarm should be displayed as specified		
9.	Vacuum pump FB fault	The vacuum pump FB fault alarm should be displayed as specified		
10.	Vacuum pump trip	The Vacuum pump trip alarm should be displayed as specified		
11.	Homogenizer motor FB fault	The Homogenizer motor FB fault alarm should be displayed as specified		
12.	Homogenizer motor trip	The Homogenizer motor trip alarm should be displayed as specified		
13.	Lobe pump FB fault	The Lobe pump FB fault alarm should be displayed as specified		
14.	Lobe Pump trip	The Lobe Pump trip alarm should be displayed as specified		
15.	Metering pump FB fault	The Metering pump FB fault alarm should be displayed as specified		



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S.No.	IESI	ACCEPTANCE CRITERIA	OBSERVATION	(ENGINEERING) (SIGN/DATE)
16.	Metering pump trip	The Metering pump trip alarm should be displayed as specified		
17.	Mechanical seal flow switch FB fault	The Mechanical seal flow switch FB fault alarm should be displayed as specified		
18.	Vacuum flow switch FB fault	The Vacuum flow switch FB fault alarm should be displayed as specified		
19.	MMT top disk open fault	The MMT top disk open fault alarm should be displayed as specified		
20.	Wax phase vessel product temperature high	The Wax phase vessel product temperature high alarm should be displayed as specified		
21.	Water phase vessel product temperature high	The Water phase vessel product temperature high alarm should be displayed as specified		
22.	Vacuum not release fault	The Vacuum not release fault alarm should be displayed as specified		
23.	Air pressure fault	The Air pressure fault alarm should be displayed as specified		
24.	MMT load capacity overloaded	The MMT load capacity overloaded alarm should be displayed as specified		
Checke Produc Sign/D	•		Verified By Quality Assi Sign/Date: .	ırance
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Inference:	
	Reviewed By
	Manager OA
	Manager QA Sign/Date:
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8.7 USER ACCESS / RIGHTS VERIFICATION

Mode		Leve (Opera		Level 2 (Supervisor)		Level 3 (Manager)		
		As specified	Actual	As specified	Actual	As specified	Actual	
I	Auto	\checkmark		\checkmark		$\sqrt{}$		
Mair	ntenance	X		X		$\sqrt{}$		
M	[anual	√		√		√		
	Edit	√		√		√		
Data Entry	Load	V		√		√		
·	Change Password	X		X		V		
Date &	Time entry	X		X		$\sqrt{}$		
Complication not com	es / Does aplies							
Observed by (Production) (Sign. / Date)								

(Production)		
(Sign. / Date)		
$\sqrt{-}$ Authorized		
X – Not authorized		
Checked By Production Sign/Date:		d By Assurance ate:
Inference:		
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8.8 SECURITY LEVEL VERIFICATION (PASSWORD PROTECTION)

User Level	Verification Criteria			Complies / Does not complies	Observed By (Sign. / Date)
Level 1	Login with correct user name and password	The system should be accessible			
(Operator)	Login with incorrect user name and password	The system should not be accessible			
Level 2	Login with correct user name and password	The system should be accessible			
(Supervisor)	Login with incorrect user name and password	The system should not be accessible			
Level 3	Login with correct user name and password	The system should be accessible			
(Manager)	Login with incorrect user name and password	The system should not be accessible			
Checked By Production Sign/Date:			Qua	ified By llity Assurance n/Date:	
Inference:					
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••••					
			Mai	iewed By nager QA n/Date:	



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8.9 POWER FAILURE VERIFICATION:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions. Press Again Login and cycle restart.		

Checked By Production Sign/Date:	Verified By Quality Assurance Sign/Date:
Inference:	
	Reviewed By
	Manager QA
	Sign/Date:



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9.0 **REFERENCES**:

- Validation Master Plan.
- Schedule M "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Draft Standard operating procedures.
- Any other Relevant Documents.



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11.0	DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:
12.0	CHANGE CONTROL, IF ANY:
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):
13.0	REVIEW (INCLUSIVE OF FOLLOW OF ACTION, IF ANT).
14.0	CONCLUSION:
15.0	RECOMMENDATION:



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16.0 ABBREVIATIONS:

°C : Degree centigrade

% : Percentage

cGMP : Current Good Manufacturing Practices

SS : Stainless Steel

ID. : Identification

Sign : Signature

LTD. : Limited

HMI : Human Machine Interface

M.C.B. : Miniature Circuit Breaker

No. : Number

OQ : Operational Qualification

QA : Quality Assurance

RPM : Rotation per Minute

SOP : Standard operating procedure

WHO : World Health Organization



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17.0 PROTOCOL POST APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE			
(QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD			
(QUALITY ASSURANCE)			