



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR MANUFACTURING VESSEL
(500 L)**

**OPERATIONAL QUALIFICATION
PROTOCOL CUM REPORT
FOR
MANUFACTURING VESSEL
CAPACITY: 500 L**

EQUIPMENT ID. No.	
LOCATION	MANUFACTURING ROOM
DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



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1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

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 manufacturing vessel 500 L 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 qualification of Manufacturing Vessel (Make:.....) installed in the Manufacturing room.
- This Protocol Cum Report will define the methods and documentation used to perform OQ activity of Manufacturing Vessel
- Successful completion of this Protocol Cum Report will verify that Manufacturing Vessel meet 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	<ul style="list-style-type: none">• Preparation, Review, Approval and compilation of the operational Qualification Protocol Cum Report.• Co-ordination with Production and Engineering to carryout Operational Qualification.• Monitoring of Operation Process.
Production	<ul style="list-style-type: none">• Review of Operational Qualification Protocol cum Report.• To Co-ordinate and support for execution of Operational Qualification study as per Protocol Cum Report.• Post Approval of Operational Qualification Protocol after Execution.
Engineering	<ul style="list-style-type: none">• Review of Operational Qualification.• To co-ordinate and support Operational Qualification Activity.• Calibration of Process Instruments.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Manufacturing vessel
Equipment	
Capacity	500 L.
Manufacturer's Name	
Supplier's Name	
Location of Installation	Manufacturing Room

6.0 EQUIPEMENT DESCRIPTION:

SS jacketed Mfg. tank and its components are designed to process pharmaceutical products in accordance with cGMP principles. Manufacturing Vessel is used for mixing of Pharmaceuticals product with bottom entry magnetic stirrer.

- Shell
- Jacket
- Spiral stiffner
- Insulation &cladding
- Stirrer
- SS panel
- Legs
- Rotating spray ball
- Compound gauge
- Sterile safety valve
- 0.2 micron plain vent filter
- Manual operated diapharagm valve
- Sparger tube
- Rupture disc



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- Halogen lamp
- Temperature sensor with transmitter
- Manual operated flush bottom diaphragm valve with sampling valve arrangement.
- Safety valve for jacket.
- PG For Jacket
- Auto Ball Valve
- Manual ball valve
- Auto steam trap unit
- Variable frequency drive
- Load cell
- Flexible hose for utility
- SS skid with castor wheel
- SS304 PLC panel



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7.0 PRE - QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of manufacturing vessel
- Draft SOP for Preventive Maintenance of manufacturing vessel.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum Report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.
Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance) Sign/Date
1.	Executed and approved Design Qualification cum report				
2.	Executed and approved Installation Qualification cum report				
3.	Draft SOP for Operation & Cleaning of manufacturing vessel				
4.	Draft SOP for Preventive Maintenance of manufacturing vessel				

Checked By (Production)
Sign/Date:

Verified By (Quality Assurance)
Sign/Date:

Inference:

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Reviewed By (Manager QA)
Sign/Date:



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8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system are in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment/Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment/ Instruments Name	Equipment/Instrument I.D.	Calibration On	Due On	Observed By Sign/Date

**Checked By
(Production)
Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:

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**Reviewed By
(Manager QA)
Sign/Date:**



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8.3 EQUIPMENT START-UP VERIFICATION

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Power Supply	415 ±10% Volts AC , 50 Hz & 3 phase		
Electrical Wiring and Earthing	Electrical Wiring should be as per Approved Drawings. Double External Earthing to Control Machine and Operator should be provided.		
Guards	Guards for all Moving Parts.		
Noise Level	Below 80 db.		
Power Supply	415 ±10% Volts AC , 50 Hz & 3 phase		
Switch ON the main incoming supply by main switch.	The light on the front panel should glow.		
Start Magnetic Stirrer through HMI	Magnetic Stirrer should start immediately.		
Turn ON the Vessel Lamp ON/OFF Turn toggle key	Vessel lamp should ON.		
Enter speed on HMI, to vary the speed of Magnetic Stirrer.	Speed of Magnetic Stirrer should change as per the speed entered in HMI.		
Pressing Green control on Push button	HMI & load cell indicator should be powered on.		
Pressing Emergency push button	Hooter should be activated with alarm message on HMI.		
Releasing Emergency push button	Alarm message should be disappeared.		
Pressing Red Control off Push button	HMI & load cell indicator should be powered off.		



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8.4 FUNCTIONAL & OPERATIONAL VERIFICATION

Instrument's Operational Verification

Immersing Product temperature sensor in known temp bath.	The same temperature value should be displayed on HMI with ± 0.1 to 0.2°C tolerance & 0.1°C incremental.		
Immersing in known temp bath. SIP drain temperature sensor	The same temperature value should be displayed on HMI with ± 0.1 to 0.2°C tolerance & 0.1°C incremental.		
Keeping standard weight on vessel Take a load of 50 kg. & 400 kg. In Load Vessel	The load cell indicator should display the same weight with The same value should be displayed on HMI.		

Steam inlet valve

Pressing steam inlet valve symbol	Steam inlet valve should be opened.		
	Red symbol should be converted into green.		
Pressing again after opening	Steam inlet valve should be closed.		
	Green symbol should be converted into Red.		

Cooling outlet valve

Pressing cooling outlet valve symbol	Cooling outlet valve should be opened		
	Red symbol should be converted into green.		
Pressing again after opening	Cooling outlet valve should be closed.		
	Green symbol should be converted into Red.		

Jacket vent valve

Pressing jacket vent valve symbol	Jacket vent valve should be opened.		
	Red symbol should be converted into green.		



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Pressing again after opening	Jacket vent valve should be closed.		
	Green symbol should be converted into Red.		
Condensate out valve			
Pressing condensate outlet valve symbol	Condensate outlet valve should be opened.		
	Red symbol should be converted into green.		
Pressing again after opening	Condensate outlet valve should be closed.		
	Green symbol should be converted into Red.		
Cooling inlet valve			
Pressing cooling inlet valve symbol	Cooling inlet valve should be opened.		
	Red symbol should be converted into green.		
Pressing again after opening	Cooling inlet valve should be closed		
	Green symbol should be converted into Red.		
Jacket drain valve			
Pressing cooling inlet valve symbol	Jacket drain valve should be opened		
	Red symbol should be converted into green.		
Pressing again after opening	Jacket drain valve should be closed.		
	Green symbol should be converted into Red.		
BAGI 1K Stirrer			
Pressing BAGI 1K stirrer symbol	BAGI 1K stirrer should be turned on.		
	Red symbol should be converted into		



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	green.		
Pressing again after turning on	BAGI 1K stirrer should be turned off.		
	Green symbol should be converted into Red.		
Vessel lamp (VL)			
Pressing vessel lamp symbol & then switch from lamp	Vessel lamp should be glow on.		
	Red symbol should be converted into green.		
Pressing again after switching on	Vessel lamp should be glow off.		
	Green symbol should be converted into Red.		
Manual Mode Mixing Process			
BAGI stirring start for entire set time.	BAGI stirrer should be turned on to run at set speed.		
	On set run time over, BAGI stirrer should be turned off.		
	Hooter should be activated with "BAGI stirring over" message.		
	On acknowledging message, hooter should be silent.		
BAGI stirring with intermediate stop	BAGI stirrer should be turned off.		
	Hooter should be activated with "BAGI stirring stopped" message.		
	On acknowledging message, hooter should be silent.		
Heating" Operation			
Heating for entire set time	Boiler steam inlet valve & condensate outlet valve should be opened.		
	BAGI stirrer should be turned on to run at set speed.		



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	As product temp .reaches the set point, heating maintain time should be started.		
	Steam inlet valve should be opened & closed to maintain heating temp.		
	On heating maintain time over, steam inlet valve , condensate outlet valve should be closed & BAGI stirrer should be turned off		
	Hooter should be activated with “Heating Over” message.		
	On acknowledging message, hooter should be silent.		
Heating with intermediate stop	Boiler steam inlet valve & condensate outlet valve should be closed.		
	BAGI stirrer should be turned off.		
	Hooter should be activated with “Heating stopped” message.		
	On acknowledging message, hooter should be silent.		
“Cooling” Operation			
Cooling for entire set time	Cooling inlet valve & cooling outlet valve should be opened.		
	BAGI stirrer should be turned on to run at set speed.		
Cooling for entire set time (Continue)	As product temp.reaches the set point, cooling maintain time should be started.		
	Cooling inlet valve should be opened & closed to maintain cooling temp.		
	On cooling maintain time over, cooling inlet valve , cooling outlet		



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	valve should be closed & BAGI stirrer should be turned off.		
	Hooter should be activated with “Cooling Over” message		
	On acknowledging message, hooter should be silent.		
Cooling with intermediate stop	Cooling inlet valve & cooling outlet valve should be closed.		
	BAGI stirrer should be turned off.		
	Hooter should be activated with “Cooling stopped” message.		
	On acknowledging message, hooter should be silent.		
“Jacket Drain” Operation			
Jacket drain start	Jacket air vent valve & jacket drain valve should be opened.		
Jacket drain stop	Jacket air vent valve & jacket drain valve should be closed		
Auto Mode Mixing Process Verification			
“On Start-up”			
Selecting & start the process	Confirming message should be displayed “Connected all required utilities to the tank?”		
“Escaping” confirming message	Process should not be started.		
Acknowledging Confirming message	Process should be commenced		
“Step-1”			
Stirring with BAGI & Ingredient Addition	“Add Ingredient” message should be displayed.		
	On acknowledging & pressing back, process should move ahead further.		



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	BAGI stirrer should be turned on to run at set speed.		
	On set process time over, BAGI stirrer should be turned off.		
“Step-2”			
Stirring with BAGI	BAGI stirrer should be turned on to run at set speed.		
Stirring with BAGI (Continue)	On set process time over, BAGI stirrer should be turned off.		
	Process should be jumped to the next step.		
“Step-3”			
Heating with BAGI run & Ingredient Addition	“Add Ingredient” message should be displayed.		
	On acknowledging & pressing back, process should move ahead further		
	BAGI stirrer should be turned on to run at set speed.		
	Boiler steam inlet valve & condensate outlet valve should be opened.		
	As product temp. reaches the set point, heating maintain time (process time) should be started.		
	Steam inlet valve (PAV2) should be opened & closed to maintain heating temp.		
	On heating maintain time (process time) over, steam inlet valve, condensate outlet valve should be closed & BAGI stirrer should be turned off.		



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	Process should be jumped to the next step.		
Heating with BAGI run	BAGI stirrer should be turned on to run at set speed.		
	Boiler steam inlet valve & condensate outlet valve should be opened.		
	As product temp.reaches the set point, heating maintain time (process time) should be started.		
	On heating maintain time (process time) over, steam inlet valve , condensate outlet valve should be closed		
	BAGI stirrer should be turned off.		
	Process should be jumped to the next step.		

“Step-5”

Cooling with BAGI run & Ingredient Addition	Add Ingredient” message should be displayed.		
	On acknowledging& pressing back, process should move ahead further.		
	BAGI stirrer should be turned on to run at set speed.		
	Cooling water inlet valve & cooling water outlet valve should be opened.		
	As product temp.reaches the set point, cooling maintain time (process time) should be started.		
	Cooling water inlet valve should be opened & closed to maintain cooling		



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	temp		
	On cooling maintain time (process time) over, cooling water inlet valve (PAV4), cooling water outlet valve (PAV3) should be closed & BAGI stirrer should be turned off.		
	Process should be jumped to the next step		
“Step-6”			
Cooling with BAGI run	BAGI stirrer should be turned on to run at set speed.		
	Cooling water inlet valve & cooling water outlet valve should be opened.		
	As product temp.reaches the set point, cooling maintain time (process time) should be started.		
	On cooling maintain time (process time) over, cooling water inlet valve , cooling water outlet valve should be closed		
	BAGI stirrer should be turned off.		
	Process should be jumped to the next step.		
“Step-7”			
Process Over	“Process Over” message should be popup with hooter activation.		
	On acknowledging, hooter should be silent.		



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Common Alarms & Interlocks Verification

Air pressure low	Air pressure low” alarm should be displayed on HMI with hooter activation.		
Emergency pressed	Emergency pressed” alarm should be displayed on HMI with hooter activation		
On acknowledging alarm,	Hooter should be silent.		
BAGI Stirrer over load	BAGI Stirrer overload” alarm should be displayed on HMI with hooter activation.		
Process Paused	Process paused” alarm should be displayed on HMI with hooter activation.		
Product temperature low	“Product temperature low” alarm should be displayed on HMI with hooter activation.		
Product temperature high	Product temperature high” alarm should be displayed on HMI with hooter activation.		
No heating is taking placed	Entire process should be aborted with alarm “No heating is taking placed, process aborted” should be displayed on HMI with hooter activation with “Heating Escape” & “Process Abort” option		
No cooling is taking placed	Entire process should be aborted with alarm “No cooling is taking placed, process aborted” should be displayed on HMI with hooter activation with “cooling Escape” & “Process Abort” option		
BAGI RPM set to Zero	BAGI stirrer should not be turned on & alarm “BAGI RPM set to zero” should be displayed on HMI with hooter activation.		



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Auto Mode Mfg with Manual Mode Mfg.	Manual mode should not be selected if auto mode process is already selected & vice versa.		
Heating with Cooling in Manual mode Mfg.	Cooling should not be started if heating is already in process & vice versa.		
Heating with BAGI stirring in Manual mode Mfg	BAGI stirring should not be started if heating is already in process & vice versa.		
Cooling with BAGI stirring in Manual mode Mfg	BAGI stirring should not be started if cooling is already in process & vice versa.		
Heating with jacket drain in Manual mode Mfg	Jacket drain should not be started if heating is already in process & vice versa.		
Cooling with Jacket drain in Manual mode Mfg	Jacket drain should not be started if cooling is already in process & vice versa.		

Security Levels Verification.

Operator Level	Operator level should have access to process selection, process start & stop in auto, manual mode, print start & stop, alarm, I/O & MIMIC visualization. It should have access to acknowledge the alarm & reset the process.		
Supervisory Level	Supervisory level should have access to operator level all menu and in addition to that, should have excess to set the process parameter, batch info, recipe preparation & recipe upload		
Engineer Level	Engineer level should have access to operator level all menu and in addition to that, should have excess to		



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	maintenance mode, control limit, & scale.		
Manager Level	Manager level should have access to supervisory level all menu and in addition to that, should have excess to change the password.		

**Checked By
(Production)**

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

Inference:

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Reviewed By

(Manager QA)

Sign/Date:



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8.5 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.		

**Checked By
(Production)
Sign/Date:**

**Verified By
(Quality Assurance)
Sign/Date:**

Inference:

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**Reviewed By
(Manager QA)
Sign/Date:**



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9.0 REFERENCES:

The Principle Reference is the following:

- Master Validation 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.

The following references are used to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, General. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals, April 1, 1998.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.

10.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Any other Relevant Documents.



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11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

%	:	Percent
AC	:	Alternate current
cGMP	:	Current Good Manufacturing Practices
ID.	:	Identification
IQ	:	Installation Qualification
LTD.	:	Limited
Ltrs	:	Liters
MFT	:	Manufacturing vessel
No.	:	Number
No.	:	Number
OQ	:	Operational Qualification
SOP	:	Standard operating procedure
°C	:	Degree centigrade
HZ	:	Hertz
HMI	:	Human machine interface



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17.0 PROTOCOL POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			