



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN COOKING VESSEL**

PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following authorities.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		



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2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of the operational qualification is to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document are the same at utmost transparency.

2.2 PURPOSE:

The purpose of this protocol is to establish the documentary evidence to ensure that the installed Gelatin Cooking Vessel shall operate reproducibly and consistently within its full dynamic range of operation according to manufacturer's specification.

2.3 SCOPE:

This protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the Gelatin Cooking Vessel operates and performs as intended in accordance with the design qualification.

The Scope of this protocol is limited to the operational Qualification of Gelatin Cooking Vessel installed in Feeding Room.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering, quality control and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The operational checks, calibration of component, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons.



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- Microbiologist shall expose the plate in bin washing machine.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering/Quality control :

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The equipment shall be operational as per its specified operating instructions
- 3.2 All SOPs for the equipment to be verified and checked
- 3.3 Training shall be given to all the concerned personnel
- 3.4 All the functionality of equipment components to be checked.
- 3.5 All the safety feature and utility to be verified and checked
- 3.6 All calibrated component to be verified and checked.

4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if

- There are any major changes in system components which affect the performance of the system
- After major breakdown maintenance is carried out.
- As per revalidation date and schedule



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5.0	OPERATIONAL QUALIFICATION PROCEDURE		
5.1	EQUIPMENT DESCRIPTION:		
1	Equipment Name	:	Gelatin Cooking Vessel
2	Supplier/Manufacturer	:	Bectochem Consultants & & Engineers Pvt. Ltd.
3	Model	:	NA
4	Serial no.	:	NA
5	Location	:	Gelatin preparation room

The basic principle utilized in the design of this gelatin cooking vessel is anchor carrying out specific function resulting in operational synergy giving most optimum mixing results.

The Gelatin Cooking Vessel consists of Following Components:

1. Gelatin Cooking Vessel comprises of vertical, cylindrical shell with welded top & bottom dishes and flange end top dish.
2. Gelatin Cooking Vessel is provided with jacket for heating the water with the help of hot water.
3. Stirrer entry at the top with the drive for the stirrer is mounted on a hinged plate at the top edge of the vessel. It will be provided with a VFD for speed variation.
4. Entire vessel is supported on 4 Nos. legs; 3 out of 4 legs for load cell and 1 for balancing.

Note:

1. All gaskets will be silicon food grade.
2. All rotating part will be covered with guard.
3. No sharp edges, easy to clean.



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5.2 INSTRUCTION FOR FILLING THE CHECKLIST

- 5.2.1 Write down the actual observation in observation column as per design specification
- 5.2.2 Observation functional parameter should be write actual function in specified column.
- 5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.
- 5.2.4 Whichever column is blank or not used 'NA' shall be used.



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5.3 TEST INSTRUMENT DETAILS

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation of the Gelatin Cooking Vessel.

S.No.	Name Of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

Checked by Date:

Remark: -----

Reviewed by (Sign/Date)



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5.4 Verification of Calibrated component :

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard, which is to be used for the verification of the operation of the Gelatin Cooking Vessel.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration Due on	Certificate number

Checked by Date:

Remark: -----

Reviewed by (Sign/Date)



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5.5 VERIFICATION OF FUNCTIONAL CHECKS:

OBJECTIVE:

To verify the working efficiency and functional checks of the Gelatin Cooking Vessel.

PROCEDURE:

TEST RUN:

Mention the details of the test run and the check point to be checked of the Gelatin Cooking Vessel during operation qualification:-

Record the observation of operation qualification in the following checklist:

NAME OF SYSTEM COMPONENT	SPECIFIED FUNCTION / ACCEPTANCE CRITERIA	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN/DATE
Feeding point	To feed the Gelatin into the vessel	By Challenging		
Light Glass	To provide light inside the vessel during processing	By Challenging		
Elliptical Manhole	To see inside the vessel during processing	By Challenging		
Vacuum Connection	For creating the Vacuum into the vessel	By Challenging		
Hose Connection	For suction of Liquid Gelatin Material	By Challenging		
Air Vent	For Vent Release	By Challenging		
Material out Let	For Prepared Gelatin Discharge	By Challenging		
Temperature Indicator	Set the Temperature of the Vessel at 80° C.	By Test Equipment		
Vacuum Pressure Gauge for vessel	Vacuum Pressure should be between 650 to 760 mm Hg	By Challenging		
Pressure Gauge for vessel	Pressure should be between 0-7 kg/cm ²	By Physically		
Water inlet	For Entering the water in the tank	By Challenging		



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NAME OF SYSTEM COMPONENT	SPECIFIED FUNCTION / ACCEPTANCE CRITERIA	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN/DATE
Stirrer speed	Shall be measured by tachometer against set rpm 1. 10 rpm 2. 20 rpm 3. Max. rpm (Full Knob)	By Test Equipment	Observed RPM: 1. _____ rpm 2. _____ rpm 3. _____ rpm	
Load Cell	Shall be verify by loading measured Quantity of water in vessel As _____ kg _____ kg _____ kg _____ kg _____ kg	By Challenging	 _____ kg _____ kg _____ kg _____ kg _____ kg	

Remark: -----

Reviewed by (Sign/Date)



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5.6 VERIFICATION OF KEY FUNCTIONAL OF MAJOR COMPONENT OF THE SYSTEM:

Following component of the system have been verified for key functionality:

Control ON/OFF:

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
By twisting the knob towards ON position	Electricity supply should be start to the panel and R, Y & B Phase indicator shall Glow .		
By twisting the knob towards OFF position	Electricity supply should be stop to the panel and R, Y & B Phase indicator shall OFF .		

Sight Lamp ON/OFF:

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
By pressing the switch towards ON position	Lamp should be Glow		
By pressing the switch towards OFF position	Lamp should be OFF		

Heat ON/OFF:

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
By twisting the main switch towards Heat position	Heating should be ON		
By twisting the switch towards OFF position	Heating should be STOP		
By twisting the switch towards COOL position	Cooling should be START		

Emergency Stop:

METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
Push Red button	Machine shall stop immediately.		



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Remark: -----

Reviewed by (Sign/Date)

5.7 VERIFICATION OF SAFETY FEATURES:

Identify and record the safety features (if any) and their function in following tables:

Safety Features Description	Function	Method of verification	Observation	Verified By (Sign & Date)
Earthing of motor	To avoid the accident due to the leakage current.	Visually		
Safety valve	To avoid the accident due to high pressure in the jacket.	Visually		

Remark: -----

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were verified as important for effective operation of the Gelatin Cooking Vessel.

S.No.	SOP title	SOP number	Verified by	Date
1.				
2.				

Remark: -----

Reviewed by (Sign/Date)



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5.9 VERIFICATION OF SUPPORTING UTILITIES:

S. No.	Utility	Method Of Verification	Observation	Checked By Sign & Date
1	Electricity: 415 V, 3 Phase, 50 Hz	Physically with clamp meter		
2	Water	Visually		
3	Steam	Visually		
4	Vacuum	Visually		

Remark: -----

Reviewed by (Sign/Date)



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5.10 TRAINING RECORD OF PERSONNEL (S):

Following person has been trained during operation qualification about machine operation and setting parameter.

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

Remark: -----

Reviewed by (Sign/Date)



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5.11 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any):

Done By & Date:

Verified By & Date:



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5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

**Deviation accepted by
(Sign/Date)**

**Deviation Approved by:
(Sign/Date)**



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5.13 Abbreviation

Following Abbreviations are used in the Operational qualification protocol of Gelatin Cooking Vessel.

MOC : Material of Construction

RPM : Rotations per Minute

OQ : Operational Qualification

Sr. : Serial

SOP : Standard Operating Procedure

No. : Number



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6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign / date**

**Checked By
Sign / date**



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6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol. (If applicable) signature in the block below indicates that all items in this qualification report of Gelatin Cooking Vessel have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved. After the successful operational qualification of the Gelatin Cooking Vessel, the equipment can be taken for performance qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		