



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

S.No.	ITEM DESCRIPTION	PAGE No.
1.0	PROTOCOL APPROVAL	2
2.0	OVERVIEW:	3
2.1	Objective	3
2.2	Purpose	3
2.3	Scope	3
2.4	Responsibility	3-4
2.5	Execution Team	5
3.0	ACCEPTANCE CRITERIA	6
4.0	REVALIDATION CRITERIA:	6
5.0	OPERATIONAL QUALIFICATION PROCEDURE	7
5.1	Equipment Description	7
5.2	Instruction for Filling the Checklist	8
5.3	Test Instrument detail	9
5.4	Verification of Calibrated component	10
5.5	Verification of Functional Checks	11
5.6	Verification of Key Functionality of Control Panel	12-13
5.7	Verification of Safety Feature (S)	14
5.8	Verification of Standard Operating Procedure	15
5.9	Verification Of Supporting Utilities	16
5.10	Training Record Of Personnel (S)	17
5.11	Annexure (s)	18
5.12	Deficiency And Corrective Action(s) Report(s)	19
5.13	Abbreviation	20
6.0	OPERATIONAL QUALIFICATION FINAL REPORT	21
6.1	Summary	21
6.2	Conclusion	21
6.3	Final Report approval	22



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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		



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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 Holding Tank (280 Liters) 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 Holding Tank (280 Liters) operates and performs as intended in accordance with the design qualification.

The Scope of this protocol is limited to the operational Qualification of Gelatin Holding Tank (280 Liters) 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.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

- 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.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

5.0 OPERATIONAL QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	Gelatin Holding Tank
Supplier/Manufacturer	:	Bectochem Consultants & Engineers Pvt. Ltd.
Model	:	NA
Serial no.	:	NA
Location	:	Feeding room

The Gelatin Holding Tank (280 Liters) consists of Following Components:

1. Gelatin Holding Tank comprises of vertical, cylindrical shell with welded bottom & lose top lid in SS 316.
2. Gelatin Holding Tank is provided with jacket for hot water circulation.
3. Water level indicator with a funnel to top up the water level in the jacket and if water level is below the heaters, then the heaters will be automatically switch **OFF**.
4. Vessel duly supported on SS bracket PEU wheels 4" dia. all swivel.
5. To avoid heat loss, 50 mm thick mineral wool of density 100 Kg/m³ is provided & cladded with 2 mm SS 304 plate.

Note:

1. No sharp edges, easy to clean.
2. Control panel should be wall mounted.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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 Holding Tank (280 Liters).

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

Checked by Date:

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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 Holding Tank (280 Liters).

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

Checked by Date:

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

5.5 VERIFICATION OF FUNCTIONAL CHECKS:

OBJECTIVE: To verify the working efficiency and functional checks of the Gelatin Holding Tank (280 Liters).

PROCEDURE:

TEST RUN:

Mention the details of the test run and the check point to be checked of the Gelatin Holding Tank (280 Liters) during operational qualification:-

Record the observation of operational qualification in the following checklist:

NAME OF SYSTEM COMPONENT	SPECIFIED FUNCTION / ACCEPTANCE CRITERIA	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN/DATE
Gelatin Holding Tank				
Working Capacity	Should be 250 Kg	By Challenging		
Ball Valve	It is used for Material discharging	By Challenging		
Water inlet / air vent	To fill water in to the jacket & for passage of air	By Challenging		
PU coated nylon castor (4 Nos.)	For movement of the tank	By moving the tank		
Material outlet	For Discharging the Material	By Challenging		

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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

Verify the key functional of the major component of the Gelatin Holding Tank (280 Liters) and record the observation in the following table:

KEY FUNCTIONAL	METHOD OF VERIFICATION	ACCEPTANCE CRITERIA	OBSERVATION	VERIFIED BY SIGN/DATE
Control ON:	By twisting the knob towards ON position	Electricity supply should be start to the panel and R, Y & B Phase indicator shall glow.		
Control OFF:	By twisting the knob towards OFF position	Electricity supply should be stop to the panel and R, Y & B Phase indicator shall OFF .		
Heater ON:	By twisting the main switch towards ON position	Heater should be start		
Heater OFF:	By twisting the main switch towards OFF position	Heater should be stop		
TEMPERATURE SENSOR:	Set the temperature of the jacket water at _____ °C and when achieve the temperature verify the temperature with test temperature sensor.	Water should achieved temperature with _____ ° C ± 5°C.		
	Set the temperature of the gelatin vessel at _____ °C and when achieve the temperature verify the temperature with test temperature sensor.	Water should achieved temperature with _____ ° C ± 5°C.		

Remark:-----

Reviewed by (Sign/Date)



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

5.7 VERIFICATION OF SAFETY FEATURES:

Verify the operation of safety features and their functionality and record the observation in the following table of the respective report:

SAFETY FEATURES DESCRIPTION	FUNCTION	METHOD OF VERIFICATION	OBSERVATION	VERIFIED BY SIGN & DATE
Earthing to the tank	To avoid the accident due to the leakage current.	Visually		

Remark:

Reviewed by (Sign/Date)



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were verified as important for effective operation of the Gelatin Holding Tank (280 Liters).

S.No.	SOP title	SOP number	Verified by (Date & Sing)

Remark: -----

Reviewed by (Sign/Date)



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

5.9 VERIFICATION OF SUPPORTING UTILITIES:

S.No.	Utility	Method Of Verification	Observation	Checked By Sign & Date
1	Electricity: 415 VAC, 3 phase, 50Hz	Physically with Clamp meter		
2	Water	Visually		

Remark: -----

Reviewed by (Sign/Date)

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)



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

5.11 Annexure (S)

Annexure No.	Details Of Annexure

Remarks (if any):

Done By & Date:

Verified By & Date:



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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)**



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

5.13 Abbreviation

Following Abbreviations are used in the Operational qualification protocol of Gelatin Holding Tank (280 Liters).

MOC : Material of Construction

RPM : Rotations per Minute

OQ : Operational Qualification

Sr. : Serial

SOP : Standard Operating Procedure

No. : Number



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign / date**

**Checked By
Sign / date**



PHARMA DEVILS

**OPERATIONAL QUALIFICATION
FOR
GELATIN HOLDING TANK**

PROTOCOL No.:

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 Holding Tank (280 Liters) 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 Holding Tank (280 Liters) 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		