



**PHARMA DEVILS**

**PERFORMANCE QUALIFICATION  
FOR  
GELATIN HOLDING TANK**

**PROTOCOL No.:**

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**1.0 REPORT 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.

This performance qualification protocol of Gelatin Holding Tank has been reviewed and approved by the following persons:

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



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**2.0 OVERVIEW:**

**2.1 OBJECTIVE:**

The objective of developing and executing this protocol is to

- Document the verification of all aspects of the equipment that can affect product quality.
- To establish, check and document the performance of equipment in the established/predetermined operating ranges.

**2.2 PURPOSE:**

The purpose of this protocol is to verify that the equipment produces the desired output. Performance qualification of the equipment is planned after the successful completion of the installation and operational qualification.

**2.3 SCOPE:**

The protocol shall define the test procedures, documentation, references and acceptance criteria to establish that the performance of the equipment shall meet the predetermined acceptance criteria.

The Scope of this protocol is limited to the performance qualification of Gelatin Holding Tank installed in Soft gel feeding room of manufacturing facility.

Once the performance qualification of Gelatin Holding Tank has been completed successfully, the equipment shall be released for the production purposes.



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**2.4 RESPONSIBILITY:**

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

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

- Prepares the performance 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 analysis of sample shall be carried out by quality control department.
- Engineering department shall support for execution.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

**Head – Quality control / Production / Engineering:**

- 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.

**2.5 EXECUTION TEAM:**



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The satisfactory operation of the Gelatin Holding Tank shall be verified by executing the performance qualification studies described in this protocol. The successfully executed protocol documents that the Gelatin Holding Tank is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Gelatin Holding Tank. Execution team comprises of:

<b>NAME</b>	<b>DESIGNATION</b>	<b>DEPARTMENT</b>	<b>SIGNATURE</b>	<b>DATE</b>

**3.0 GENERAL CONSIDERATION/PREREQUISITE:**

- 3.1** Approved Standard operating procedure of Gelatin Holding Tank.
- 3.2** The impact analysis of the equipments shall be recorded in the summary sheet.
- 3.3** The installation and operational qualification of Gelatin Holding Tank shall be successfully completed before the execution of the performance qualification.
- 3.4** All the deficiencies and discrepancies related to Gelatin Holding Tank which affects the product quality and corrective action taken shall be recorded in the appropriate section of the report.
- 3.5** After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.



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**4.0 REVALIDATION CRITERIA:**

The machine shall be requalified if

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

**5.0 PERFORMANCE QUALIFICATION PROCEDURE:**

**5.1 EQUIPMENT DESCRIPTION:**

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/m<sup>3</sup> is provided & cladded with 2 mm SS 304 plate.



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**5.2 RISK ANALYSIS:**

- The gelatin holding tank is used for holding/ feeding/mixing purpose of gelatin mass.
- During the process the temperature of the holding tanks are maintained to facilitate the filling process and keep gelatin in molten stage.

S.No.	Risk identified	Control measures
1.	Temperature of the product	Temperature is regulated by digital temperature controller.
2.	Temperature of the jacket	Temperature is regulated by digital temperature controller.

**EVALUATION AND CONCLUSION:**

All the risks associated with Gelatin Holding Tank (280 Liters) have been evaluated and control/preventive measures have been taken.

**5.3 METHODOLOGY:**

Methodology of the gelatin holding is as follows:

- Gelatin Holding Tanks are used to collect the gelatin mass at many stages in the process e.g. collect the gelatin after gelatin mass, for colour mixing, to hold the gelatin for maturation after colour mixing, as holding vessel and as feeding vessel.
- Maintain the temperature of Gelatin Holding Tank at  $60^{\circ}\text{C} \pm 5^{\circ}\text{C}$ .
- The PQ of the Gelatin Holding Tanks shall be done on PQ Batch manufactured under BMR No. \_\_\_\_\_
- Maximum holding of gelatine shall be hold upto 225 liters.

**5.4 PRODUCT DETAILS:**

Product details shall be verified from the BMR of the product and record in the following table:

S.No.	Name of Product	Batch No.	Batch Size

**Remark:** -----  
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**Reviewed by (Sign/Date)**

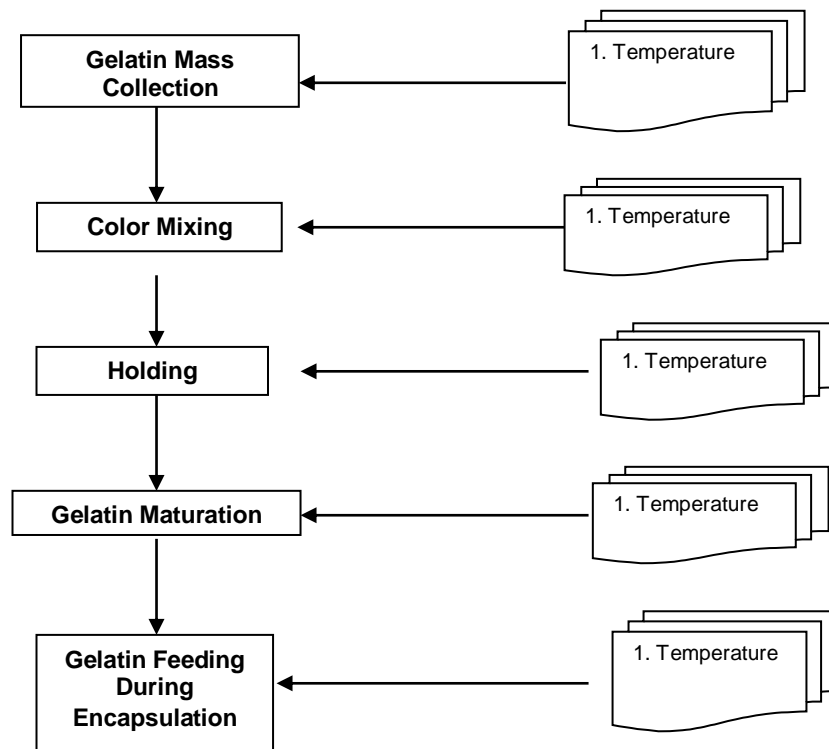


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**5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF  
GELATIN HOLDING TANK:**

Process flow diagram of Gelatin Holding Tank (280 Liters) is mentioned below:







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**5.6 SAMPLING PLAN:**

No sampling is required in the Performance Qualification of the Gelatin Holding Tank (280 Liters).

**5.7 ACCEPTANCE CRITERIA:**

The test will be considered failed if the actual test results do not correspond to the expected results as following:

- Product Temperature of Gelatin Holding tank should be within  $60 \pm 5^{\circ}\text{C}$  throughout the process.
- Gelatin should be in molten state throughout the process.

**5.8 TEMPERATURE MONITORING OF GELATIN HOLDING TANK:**

**5.8.1 Temperature Monitoring of Gelatin Holding Tank Colour Mixing Process:**

Date	Batch No.	Time	Process Temperature (°C)	Jacket Temperature (°C)	Checked By

**Remark:** -----  
-----  
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**Reviewed by (Sign/Date)**



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**5.8.2 Temperature Monitoring of Gelatin Holding Tank during Gelatin Maturation:**

Date	Batch No.	Time	Process Temperature (°C)	Jacket Temperature (°C)	Checked By

**Remark:** -----  
-----  
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**Reviewed by (Sign/Date)**



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**5.8.3 Temperature Monitoring of Gelatin Holding Tank during Holding and Encapsulation:**

Date	Batch No.	Time	Process Temperature (°C)	Jacket Temperature (°C)	Checked By

**Remark:** -----  
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**Reviewed by (Sign/Date)**



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**6.0 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**

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



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**7.0 PERFORMANCE QUALIFICATION FINAL REPORT:**

**7.1 SUMMARY:**

**7.2 CONCLUSION:**

**Prepared By  
Sign/ Date**

**Checked By  
Sign/ Date**



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**7.3 FINAL REPORT APPROVAL**

The final report shall be signed after verifying that all the tests required in the qualification report of Gelatin Holding Tank are completed, reconciled and attached to the Qualification report or included in the qualification summary report and also verified that all amendments and discrepancies are documented, approved and attached to respective report (If applicable) Signature in the block below indicates that all items in the qualification report of Gelatin Holding Tank have been reviewed and found to be acceptable and that all variations or discrepancies (if any) have been satisfactorily resolved.

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