PHARMA DEVILS	PERFORMANCE QUALIFICATION FOR GELATIN HOLDING TANK	PROTOCOL No.:

1.0 PROTOCOL APPROVAL:

Signing of this approval page of reports 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 report cannot be used for execution unless approved by the following authorities.

This Performance Qualification report of Gelatin Holding Tank (280 Liters) has been reviewed and approved by the following persons:

This Performance Qualification protocol of Gelatin Holding Tank (280 Liters) has been reviewed and approved by the following signatories:

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

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to check and document the performance of equipment in the established/predetermined operating ranges.

2.2 PURPOSE:

The purpose of this protocol is to provide the documented evidence that the functions of the equipment, which affect the product quality, integrity and safety of operating and maintenance personnel is taken into consideration.

2.3 SCOPE:

The scope of protocol shall define the test procedures, documentation and acceptance criteria to establish that the performance of Gelatin Holding Tank (280 Liters) installed in soft gel area of ……..

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 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 (wherever applicable).
- 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:

The satisfactory operation of the Gelatin Holding Tank (280 Liters) shall be verified by executing the performance qualification studies described in this report of the Gelatin Holding Tank (280 Liters). The successfully execution of the instructions mentioned in the report of the Gelatin Holding Tank (280 Liters) documents that the Gelatin Holding Tank (280 Liters) is operational and is satisfactorily working.

Execution team is responsible for the execution of performance qualification of the Gelatin Holding Tank (280 Liters).

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 GENERAL CONSIDERATION/PREREQUISITE

3.1 Approved Standard operating procedure of the Gelatin Holding Tank shall be available.

3.2 The installation and operational qualification of the equipment shall be successfully completed before the execution of the performance qualification.

3.3 All the deficiencies and discrepancies related to the equipment which affect the product quality and corrective action taken shall be recorded in the appropriate section of the protocol.

3.4 After completion of PQ activities, equipment shall be cleaned as per respective cleaning SOP's and released for manufacturing.

4.0 REVALIDATION CRITERIA:

The machine shall be re-qualified if

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

5.0 PERFORMANCE QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

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

(A) Gelatin Holding Tank comprises of vertical, cylindrical shell with welded bottom & lose top lid in SS 316.

(B) Gelatin Holding Tank is provided with jacket for hot water circulation.

(C) 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**.

(D) Vessel duly supported on SS bracket PEU wheels 4" dia. all swivel.

(E) Control Panel is mounted in gelatin Holding Tank.

5.2 RISK ANALYSIS

(A)The gelatin holding tank is used for holding/ feeding/mixing purpose of gelatin mass.

(B) During the process the temperature of the holding tanks are maintained to facilitate the filling process and keep gelatin in molten stage.

Risk identified	**Control measures**
Temperature of the product	Temperature is regulated by digital temperature controller.
Temperature of the jacket	Temperature is regulated by digital temperature controller.

EVALUATION & 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, 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°C ± 5°C.
- The PQ of the Gelatin Holding Tanks shall be done on PQ Batch manufactured under BMR No. _____ .
- Maximum holding of Gelatin shall be hold up to 250 liters.

5.4 PRODUCT DETAILS:

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

Inference:

_____

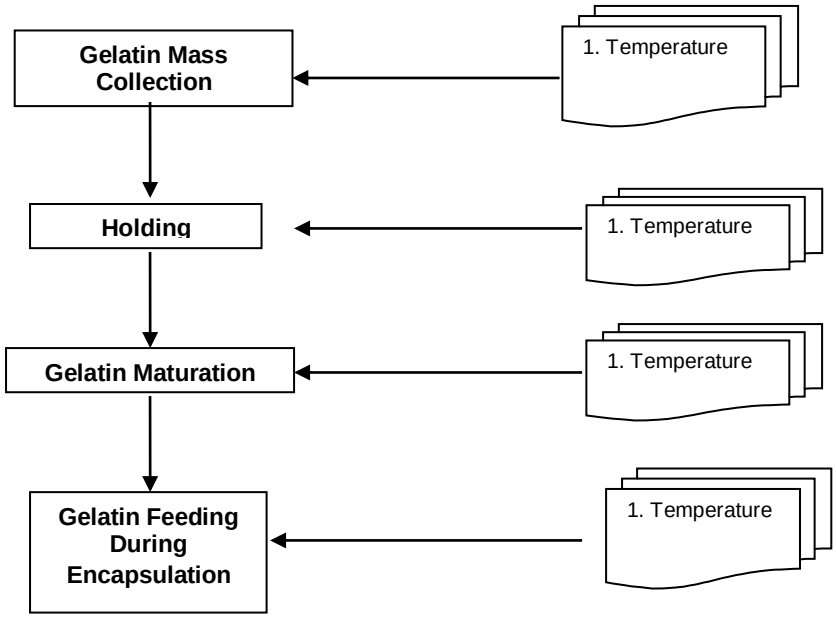
_____

_____

Reviewed By
Sign & Date

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

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



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±5°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:

Date	Batch No.	Time	Process Temperature (^{o}C)	Jacket Temperature (^{o}C)	Checked by

Inference:

_____

_____

_____

Reviewed By
Sign & Date

5.8.2 Temperature Monitoring of Gelatin Holding Tank During Gelatin Maturation:-

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

Inference:

_____

_____

_____

Reviewed By
Sign & Date

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

Inference:

_____

_____

_____

Reviewed By
Sign & Date

6.0 DEFICIENCY AND CORRECTIVE ACTION(S) REPORT(S):

Following deficiency was verified and corrective actions taken.
Description of deficiency:
Corrective action(s) taken :

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

7.0 PERFORMATION QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/Date

7.3 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 performance qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol.

Signatures in the block below indicate that all items in the qualification report have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

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