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

1.0 REPORT APPROVAL:

Signing of this approval page of report 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 signatories.

This Performance Qualification Report of Gelatin Cooking Vessel 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

- 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.

The equipment working capacity is recommended by manufacturer challenged by charging the tablets with the maximum and minimum capacity of the pan.

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 Cooking Vessel manufacturing facility at ……..

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

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:

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

Execution team is responsible for the execution of performance qualification of the Gelatin Cooking Vessel. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 PREREQUISITE

3.1 Approved Standard operating procedure of the equipment shall be available.

3.2 The maximum and minimum capacity of the equipment shall be verified by taking the batch/lot to suit the requirement.

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

3.4 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.

3.5 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-validated 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 BRIEF DESCRIPTION OF EQUIPMENT

The Gelatin Cooking Vessel consists of following components:

1. Gelatin Cooking Vessel comprises of vertical, cylindrical shell with welded top & bottom torrispherical dishes and flange end top dish.
2. Gelatin Cooking Vessel is provided with jacket for heating the 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.

5.2 RISK ANALYSIS:

- Machine is designed to operate on high speed & negative pressure.
- A safety valve is installed on the jacket to avoid any damage due to high pressure.
- A speed reducer is installed to avoid the overheating of motor.
- A over load relay is installed to avoid any damage due to the over load.

S.No.	Risk identified	Control measures
1.	Damage due to high pressure	A pressure gauge and safety valve is installed on the jacket to avoid any damage due to high pressure.
2.	Over heating of motor	A speed reducer is installed to avoid the overheating of motor.
3	Over loading on the motor	A over load rely is installed to avoid any damage due to the over load.
4	Temperature of the jacket and vessel	Separate temperature sensors for jacket and vessel to control the temperature.

EVALUATION & CONCLUSION

All the risks associated with Colloidal Mill have been evaluated and control/preventive measures have been taken.

5.3 METHODOLOGY:

Read all notes for each steps before beginning the test steps. Verify and record verification of all critical operational functions. Challenge each of the control system and each sub system. Any function, system or subsystem that fails a particular challenge should be identified and corrected before proceeding to the next section of the testing criteria. Any modification to the equipment to enable compliance with the operation, process or Qualification Protocol must be documented and approved prior to completion of the challenged section. Any modification that has an effect to the operation of the equipment must be challenged. Each challenge shall be generated and approved by each department.

- PQ batches of minimum and maximum batch sizes shall be manufacture to evaluate the performance of the Gelatin Cooking Vessel.
- The Gelatin mass shall be manufactured as per BMR No. _____ & BMR No. _____ for minimum and maximum batch sizes respectively.
- Batch No. of minimum and maximum batch sizes shall be **300 kg & 650 kg** respectively.
- Details of the PQ batches shall be mentioned under the heading of "**Product Details**".
- Start the Gelatin mass preparation as per the BMR.
- Samples shall be sent to the QC Department for analysis.

5.3.1 The sampling plan is as following:

Sampling Position	Tools	Sample Quantity	Test required
Top	**Glass beaker** for consistency & **Petri Dish** for air bubble	50 gm	Description, LOD
Middle	**Glass beaker** for consistency & **Petri Dish** for air bubble	50 gm	Description, LOD
Bottom	**Glass beaker** for consistency & **Petri Dish** for air bubble	50 gm	Description, LOD
Composite	**Glass beaker** for consistency & **Petri Dish** for air bubble	50 gm	Description, LOD

5.4 PRODUCT PROFILE:

Product details of minimum and maximum batch size shall be verified from the BMR of the product and record in the following section:

(A) Product Details of minimum batch Size:

Product Name : _____

Product Code : _____

Batch Number : _____

Batch Size : _____

Mfg. Date : _____

Exp. Date : _____

BMR Number : _____

(B) Product Details of maximum batch Size:

Product Name : _____

Product Code : _____

Batch Number : _____

Batch Size : _____

Mfg. Date : _____

Exp. Date : _____

BMR Number : _____

Inference:

_____

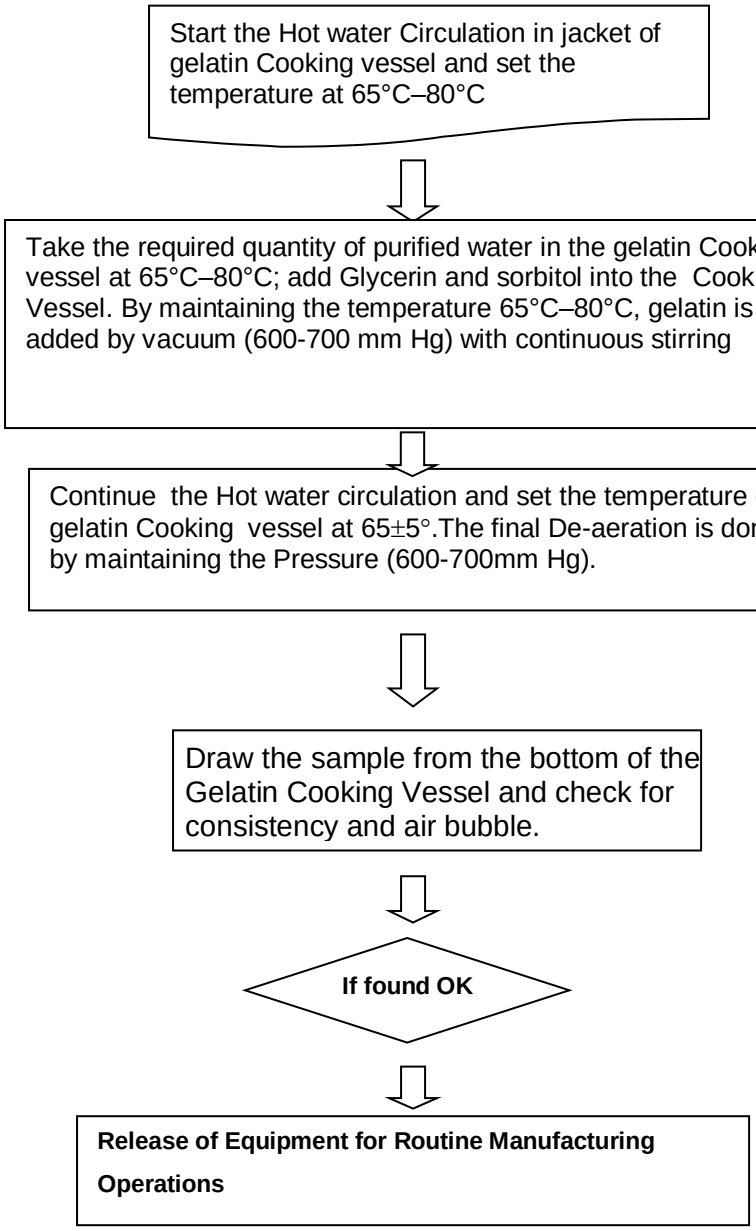
_____

_____

Reviewed By
Sign & Date

5.5 PROCESS FLOW DIAGRAM WITH QUALIFICATION PARAMETERS OF GELATIN COOKING VESSEL:-

Process flow diagram of Gelatin Cooking vessel is mentioned below:



5.6 SET PARAMETERS:

S.No	Process Steps	Process Parameters	Monitoring Parameters	Control Checks
1.	Gelatin mass preparation	i) Process Time: 3-4 hrs ii) RPM of agitator: 30-35 iii) Product temperature: 60ºC to 70ºC iv) Jacket temperature: 65ºC to 80ºC	i) Sequence of loading ii) Jacket temperature iii) Product temperature	Record the parameter
2.	De-aeration	i) Time: 40-45 minutes ii) RPM of agitator: 15 RPM iii) Temperature: 60ºC to 70ºC iv) Vacuum: 600 to 700 mm Hg	i) Air Bubble ii) Consistency	Visual inspection Viscosity

5.7 ACCEPTANCE CRITERIA:

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

- No air bubble and foreign particle should be found in visual inspection.
- Viscosity in Brook-field viscometer should be between 1000 to 16000 cps.
- No lumps of gelatin mass should be found in visual inspection.

5.8 RECORDING OF SAMPLING:

Batch No.: _____ **Date: / /**

S.No.	Date	Sampling Details	Quantity	Sampled By (Sign & Date)

Batch No.: _____ **Date: / /**

S.No.	Date	Sampling Details	Quantity	Sampled By (Sign & Date)

5.9 OBSERVATIONS AND RESULTS OF CHALLENGE TESTS:

5.9.1 Observations and Results of Minimum Batch Size:

Batch No.: _____ **Date: / /**

S.No.	Test Performed	Observation				Done By (Sign/Date)
		Top	Middle	Bottom	Composite	
1.	Description of gelatin mass					
2.	LOD					
3.	Weight per ml					
4.	Viscosity					

5.9.2 Observations and Results of Maximum Batch Size

Batch No.: _____ **Date: / /**

S.No.	Test Performed	Observation				Done By (Sign/Date)
		Top	Middle	Bottom	Composite	
1.	Description of gelatin mass					
2.	LOD					
3.	Weight per ml					
4.	Viscosity					

Inference:

_____

_____

_____

Reviewed By
Sign & Date

5.10 IN-PROCESS CHECKS DURING GELATIN MASS PREPARATION:

5.10.1 In-process Checks of Minimum Batch Size:

Batch No.: _____ **Date: / /**

S.No.	Time	Agitator Speed (RPM)	Product Temperature (°C)	Jacket Temperature (°C)	Checked By

In Process Checks during Gelatin Mass De-Aeration

Sr. No.	Time	Agitator Speed (RPM)	Product Temperature (°C)	Vacuum Pressure (in mm Hg)	Checked By

Inference:

_____

_____

_____

Reviewed By
Sign & Date

5.10.2 In Process Checks of Maximum Batch Size:

Batch No.: _____ **Date: / /**

S.No.	Time	Agitator Speed (RPM)	Product Temperature (°C)	Jacket Temperature (°C)	Checked By

In Process Checks during Gelatin Mass De-Aeration:

S.No.	Time	Agitator Speed (RPM)	Product Temperature (°C)	Vacuum Pressure (in mm Hg)	Checked By

Inference:

_____

_____

_____

Reviewed By
Sign & Date

5.11 ENVIRONMENTAL MONITORING DURING GELATIN MASS PREPARATION:

Limit: Temperature (°C) : _____ ± ___°C Relative Humidity (%) : _____ ± ___ %

Date	Time	Batch No.	Temperature (°C)	Relative Humidity (%)	Remark

Inference:

_____

_____

_____

Reviewed By
Sign & Date

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
(Sign/Date)

Deviation Approved by
(Sign/Date)

7.0 PERFORMANCE QUALIFICATION FINAL REPORT:

7.1 SUMMARY:

7.2 CONCLUSION:

Prepared By
Sign/ Date

Checked By
Sign/ Date

7.3 FINAL REPORT APPROVAL

The final report shall be signed after verifying that all the tests required in the qualification report of Gelatin Cooking Vessel 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 Cooking Vessel 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		