



PHARMA DEVILS

**INSTALLATION 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.

This Installation Qualification protocol of Gelatin Cooking Vessel has been reviewed and approved by the following persons:

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 developing and executing this protocol is to collect sufficient data pertaining to the Gelatin cooking vessel and define the installation qualification requirements and acceptance criteria for the Gelatin cooking vessel. Successful completion of these installation qualification requirements will provide assurance that the Gelatin cooking vessel was installed as required in the manufacturing area.

The Qualification of Gelatin cooking vessel performed in view of Soft gel gelatin preparation area of manufacturing facility.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Gelatin cooking vessel received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

This Protocol is applicable to installation of Gelatin cooking vessel in soft gel gelatin preparation area of the manufacturing facility.

2.4 RESPONSIBILITY:

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

Execution Team (Comprising members from Production, 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.



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- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons
 - The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – 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 installation of the Gelatin cooking vessel shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Gelatin cooking vessel is installed satisfactorily.

Execution team is responsible for the execution of installation of Gelatin cooking Vessel.

Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The Gelatin cooking vessel shall meet the system description given in design qualification.
- 3.2 The Gelatin cooking vessel shall meet with the acceptance criteria mentioned under the topic “Identification of major components”
- 3.3 All material of constructions of the contact parts to be checked as per the specifications.

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 INSTALLATION QUALIFICATION PROCEDURE:

5.1 SYSTEM 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 In case of identification of major component actual observation should be written in specified location.
- 5.2.2 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.3 For identification of utilities actual observation should be written in specified location.
- 5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.
- 5.2.5 Actual observation of the component should be written in specified location.
- 5.2.6 Whichever column is blank or not used 'NA' shall be used.



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5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method Of Verification	Actual Observation	Checked By Sign/Date
1	Verify purchase order copy and write down P.O. number	Visually/ Documental		
2	Verify that the "As Built" drawing is complete and represents the design concept.	Visually/ Physically		
3	Verify that there is no observable physical damage	Physically		
4	Examine All access ports are cleared of any debris.	Physically		
5	Verify that all components are properly assembled, securely anchored and shock proof.	Physically		
6	Verify that all electrical connections are properly done and safe	Physically		
7	Verify that the equipment is properly earthed	Physically		
8	Verify that utility line is properly connected	Physically		
9	Verify the proper leveling of equipment	Physically		
10	Verify that there is sufficient space provided for operation, cleaning, preventive maintenance	Physically		
11	Equipment/system identification no. Is visible	Physically		
12	Any sharp or rough edges	Visually		

Remark: -----

Reviewed by (Sign/Date)



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5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Describe each critical component and check them and fill the inspection checklist.

Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
Gelatin Cooking Vessel	Make	BCEPL	Visually on name plate		
	Qty.	01 No.	Visually / Physically		
	Gross Capacity	1100 ltrs.	Physically/ Technical Specification		
	Working Capacity	880 ltrs.	Physically		
Main Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Top Dish End	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		
Bottom Dish End (Bowl)	Make	BCEPL	Physically/ Technical Specification		
	Size	8 Thk.	Physically/ Technical Specification		
Jacket Shell	Make	BCEPL	Physically/ Technical Specification		
	Size	5 Thk.	Physically/ Technical Specification		
Jacket Dish	Make	BCEPL	Physically/ Technical Specification		
	Size	6 Thk.	Physically/ Technical Specification		



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Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
Insulation Shell/ Dish	Make	BCEPL	Physically/ Technical Specification		
	Size	2 Thk.	Physically/ Technical Specification		
Body Flange	Make	BCEPL	Physically/ Technical Specification		
	Size	25 mm	Physically/ Technical Specification		
Support Bracket Plate	Make	BCEPL	Physically/ Technical Specification		
	Size	20 mm	Physically/ Technical Specification		
Motor	Make	Bharat Bijlee	Physically		
	Spec.	10 HP, 1450 RPM, NON FLP	Physically		
	Sr. No.	To be recorded	Physically		
Gear Box	Make	NORD	Physically		
	Spec.	SK 9042.1 AXF IEC 132 Ratio- 40.54	Physically		
	Sr. No.	To be recorded	Physically		
Mechanical Seal	Make	HI-FAB	Physically/ Technical Specification		
	Spec.	SSDB E2	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically		
Anchor Shaft	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø80	Physically/ Technical Specification		
Anchor Sweep	Make	BCEPL	Physically/ Technical Specification		



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Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
	Size	Ø 1250 X 12 Thk.	Physically/ Technical Specification		
Paddle Sweep	Make	BCEPL	Physically/ Technical Specification		
	Size	Ø 1500 X 10 Thk.	Physically/ Technical Specification		
Baffle pipe	Make	BCEPL	Physically/ Technical Specification		
	Size	40 NB X SCH 40	Physically/ Technical Specification		
Baffle plate	Make	BCEPL	Physically/ Technical Specification		
	Size	10 Thk.	Physically/ Technical Specification		
Pressure Gauge	Location	Jacket Vent	Physically		
	Make	Baumer	Physically		
	Spec.	0-7 kg/cm ²	Physically		
Vacuum Pressure Gauge	Location	Cooking vessel	Physically		
	Make	Baumer	Physically		
	Spec.	0-760 mmHg	Physically		
Load Cell	Make	Mettle Toledo	Physically		
	Model	SBH-1 P/N71204083	Physically		
	Sr. No.	To Be Recorded	Physically		
Control Panel					
R-Phase Indicator	Make	Vishnu	Physically		
Y- Phase Indicator	Make	Teknic	Physically		



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Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
	Make	Teknic			
B - Phase Indicator	Make	Teknic	Physically		
VFD for Motor	Make	ABB	Physically		
	Model	ACS550-01-0150A-4	Physically/ Technical Specification		
	Spec.	7.5-5.5 KW	Physically/ Technical Specification		
	Sr. No.	To be recorded	Physically/ Technical Specification		
Rotary Main Switch	Make	Salzer	Physically/ Technical Specification		
Heat Off/Cool selector Switch	Make	Siemens	Physically		
	Type	3SB5400-0B	Physically		
Temperature Controller	Make	Selec	Physically		
	Model	TC-203	Physically		
	Sr. No.	To be recorded	Physically		
RPM Meter	Make	Selec	Physically		
	Model	PIC101	Physically		
	Sr. No.	To be recorded	Physically		
Anchor motor START push Button (Green)	Make	Teknic	Physically		
	Type	S1	Physically		
Anchor motor STOP push Button (Red)	Make	Teknic	Physically		
	Type	S2	Physically		
Vacuum Pump START (Green)	Make	Teknic	Physically		
	Type	S1	Physically		
Vacuum Pump STOP (Red)	Make	Teknic	Physically		
	Type	S2	Physically		



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Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
Stirrer Speed Knob	Make	Pourns	Physically		
	Spec.	3590-S-2-502L	Physically		
Vessel light selector switch	Make	Teknic	Physically		
	Type	S1	Physically		
Emergency push Button	Make	Teknic	Physically		
	Type	S2	Physically		
Fan	Make	Rexiord	Physically		
	Model	REC- 22038-A2	Physically		
START Button (Green)	Make	Esbee	Physically		
	Model	IEC 60947-5-1	Physically		
STOP Button (Red)	Make	Esbee	Physically		
	Model	IEC 60947-5-1	Physically		
Load cell Display	Make	Mettle Toledo	Physically		
	Model	TWS 300 Series	Physically		
Nozzles					
N1	Location	Elliptical Manhole	Physically		
	Size	Ø 300/400, 6 Thk.	Physically/ Technical Specification		
N2	Location	Product inlet	Physically		
	Size	3" X14 SWG	Physically/ Technical Specification		
N3	Location	Bottom Outlet	Physically		
	Size	Ø 75	Physically/ Technical Specification		
N4	Location	Vent	Physically		
	Size	Ø 38 X 14 SWG	Physically/ Technical Specification		



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Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
N5	Location	Spray Ball Connection	Physically		
	Size	Ø 50 X14 SWG	Physically/ Technical Specification		
N6	Location	Spray Nozzle Inlet	Physically		
	Size	Ø 75 X14 SWG	Physically/ Technical Specification		
N7	Location	Vacuum	Physically		
	Size	Ø 50 X14 SWG	Physically/ Technical Specification		
N8	Location	Hot Water Inlet / Cold Water Outlet	Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		
N9	Location	Hot Water Outlet / Cold Water Inlet	Physically		
	Size	25 NB X SCH 40	Physically/ Technical Specification		
N10	Location	Jacket Vent	Physically		
	Size	20 NB X SCH 40	Physically/ Technical Specification		
N11	Location	Jacket Drain	Physically		
	Size	½” NB X SCH 40	Physically/ Technical Specification		
N12	Location	Thermowell	Physically		
	Size	½” NB X SCH 40	Physically/ Technical Specification		
N13	Location	Spare	Physically		
	Size	Ø 38 X14 SWG	Physically/ Technical Specification		



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Name of System Component	Design Specification		Method Of Verification	Observation	Verified By Sign/Date
N14	Location	Light Glass	Physically		
	Size	Ø 100	Physically/ Technical Specification		

Remark: -----

Reviewed by (Sign/Date)



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5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Name Of Components	Material Of Construction	Method Of Verification	Observation	Verified By Sign/Date
Main Shell	SS 316 L	By Molybdenum Kit/ Test Certificate		
Top Dish End	SS 316 L	By Molybdenum Kit/ Test Certificate		
Bottom Dish End (Bowl)	SS 316 L	By Molybdenum Kit/ Test Certificate		
Body Flange	SS 316	By Molybdenum Kit/ Test Certificate		
Jacket Shell	SS 304	By Molybdenum Kit/ Test Certificate		
Jacket Dish	SS 304	By Molybdenum Kit/ Test Certificate		
Insulation Shell/Dish	SS 304	By Molybdenum Kit/ Test Certificate		
Mechanical Seal	SS 316	By Molybdenum Kit/ Test Certificate		
Anchor Shaft	SS 316	By Molybdenum Kit/ Test Certificate		
Paddle Sweep	SS 316	By Molybdenum Kit/ Test Certificate		
Paddle Plate	SS 316	By Molybdenum Kit/ Test Certificate		
Name Of Components	Material Of Construction	Method Of Verification	Observation	Verified By Sign/Date
Anchor Sweep	SS 316	By Molybdenum Kit/ Test Certificate		
Baffle Pipe	SS 316	By Molybdenum Kit/ Test Certificate		
Baffle Plate	SS 316	By Molybdenum Kit/ Test Certificate		
Nozzles (N1-N7, N13 & N14)	SS 316L	By Molybdenum Kit/ Test Certificate		
Nozzles (N8-N12)	SS 304	By Molybdenum Kit/ Test Certificate		

Remark: -----

Reviewed by (Sign/Date)



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5.6 IDENTIFICATION 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)

5.7 IDENTIFICATION OF SAFETY FEATURES:

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

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

Remark: -----

Reviewed by (Sign/Date)



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5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED

Name of Components	Range	Make	ID	Location	Identified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)



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5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)

The following Standard Operating Procedures were identified as important for effective performance of Gelatin cooking vessel operation.

S.No.	SOP Title	Verified By Sign/ Date

Remark: -----

Reviewed by (Sign/Date)



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5.11 ABBREVIATIONS

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

MOC : Material of construction

V : Volts

HZ : Hertz

mm : Millimeter

Spec. : Specification

Qty. : Quantity

ltrs. : Liters

BCEPL: Bectochem Consultants & Engineers Pvt. Ltd.

NA: Not applicable

Thk.: Thickness

GMP: Good manufacturing Practice



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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 Annexure (S)

Annexure No.

Details Of Annexure

Remarks (if any): -----

Done By & Date:

Verified By & Date:



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6.0 INSTALLATION 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. 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 installation qualification of the Gelatin cooking vessel the equipment can be taken for operational qualification.

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