



**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
PASTE KETTLE
(CAPACITY- 200 LITRES)**

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

CONTENTS

S.No.	TITLE	PAGE No.
1.0	Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Brief Equipment Description	6
6.0	Equipment Specification	6
7.0	Critical Variables to be Met	7
7.1	Process / Product Parameters	7
7.2	Utility Requirement / Location Suitability	7
7.3	Technical Specification /Key Design Features	8
7.4	Material of Construction	12
7.5	Safety	12
7.6	Vendor Selection	13
8.0	Documents to be Attached	13
9.0	Review (Inclusive of Follow Up Action, If Any)	14
10.0	Any Changes Made Against the Formally Agreed Parameters	14
11.0	Recommendation	14
12.0	Abbreviations	15
13.0	Reviewed By	16



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for Paste Kettle with cGMP Model procured from Bectochem for
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	<ul style="list-style-type: none">• Preparation, Review and Approval of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Post Approval of Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Post Approval of Qualification Protocol cum Report after Execution
Engineering	<ul style="list-style-type: none">• Review of the Protocol cum Report.• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings, as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing➤ Specification of the sub-components/ bought out items, their Make, Model, Quantity and backup records / brochures.➤ Details of Utilities➤ Identification of components for calibration➤ Material of construction of all components➤ System Description➤ Safety Features and Alarms• Post Approval of Qualification Protocol cum report after Execution.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

5.0 BRIEF ABOUT EQUIPMENT:

Paste kettle is designed as per good manufacturing practice in terms of clean ability of components, surface finish, absence of sharp corners, assembling and de-assembling of components and control devices. Machine should be designed to be of jacketed type, electrically or steam heated, thermostatic control with the unit, safety valve, insulated with suitable insulating material, tilting with hand wheel. Easy transfer of paste while tilting, unit should be provided with suitable lid to discharge. Bottom valve for steam water, which should be easily removable and easily cleanable.

MAIN FEATURES

- All contact part made of SS 316 as per GMP standard
- Hemispherical design for proper mixing of paste.
- Jacket provided with steam/Electrical heating arrangement.
- Tilting arrangement for kettle is provided for discharge for starch paste.
- Anchor type impeller design for proper mixing of paste.
- Safe earthing system.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specification is based on User Requirement Specification document is prepared by The manufacturer of equipment ensures complies with User Requirement Specification.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Paste Kettle shall be able for preparation of binder materials used in medicine preparation.	The Paste Kettle should be able for preparation of binder materials used in medicine preparation.	Process Requirement
Working: Working of Paste Kettle	Paste Kettle should capable of preparation of binder materials as per product requirement.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITY REQUIREMENTS / LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in service area.	cGMP Requirement
Room Condition	Temperature and RH requirement as per requirement of product	Process Requirement



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

S.No.	Name of Component	Technical Specification
1.	Model	GMP Model
2.	Capacity	Working : 200 Ltr Gross : 160 Ltr
3.	Dimension	1275L x 1000 W x 1880 H in mm
4.	All Contact parts	SS316
5.	Non contact parts	SS304
6.	Motor	<ul style="list-style-type: none">• Make: REMI• HP: 3 HP• RPM: 1440• VOLT: 415 ± 10%• PHASE: 3PH
7.	Gear Box	<ul style="list-style-type: none">• Make: "SUDARSHAN GEARS"• Type: Worm Reduction Type• Ratio: 30:1
8.	Agitator	<ul style="list-style-type: none">• Shape: Anchor Type• RPM: 30-200• Shaft: SS 304• Coupling: fanner type• Sealing: single dry mechanical seal
9.	Bowl Dimension	<ul style="list-style-type: none">• Shell : 700 mm ID x 540 mm HT x 4 thk• Jacket : 850 mm ID x 380 mm HT x 2mm thk• Cladding: 16 SWG fully covering the jacket. Welding type• Locking: 2 Nos. locking pins with top cover to align bowl in position
10.	Tilting Arrangement	<ul style="list-style-type: none">• Type : mechanical• Hand wheel with bevel gear arrangement
11.	Nozzle Schedule	<ul style="list-style-type: none">• Jacket inlet with QRC- 25 BSP• Safety valve : 15 BSP



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

S.No.	Name of Component	Technical Specification
		<ul style="list-style-type: none">• Jacket Outlet With QRC : 20 BSP• Jacket Drain : 20 BSP- with blind• Thermo well: 20 BSP- PT-100 Sensor• Jacket Vent: 15 BSP- with needle valve• Bottom Outlet: 100 With Flush Type Valve Manually Operated• Steam inlet: 20 NB
12.	Finish	<ul style="list-style-type: none">• Internal : 240 Grit mirror• External: 180 Grit matt
13.	Main Bowl & shell	Make: BLPTPL MOC: 10 SWG (SS 316)
14.	Jacket Bowl	Make: BLPTPL MOC: 10 SWG(SS 304)
15.	Insulation Bowl	Make: BLPTPL MOC: 14 SWG(SS 304)
16.	Stand	Make: BLPTPL MOC: 10 SWG(SS 304) Dimension: 80 x 80 x10
17.	Plummer Block	Make: ZKL MODEL: UCP-211
18.	Top Lid	Make: BLPTPL MOC: 14 SWG(SS 316)
19.	VFD For geared motor	Make: ABB Volt: 3 HP
20.	Anchor blade & shaft	Make: BLPTPL MOC: (SS 316) Dimension: 50x10 Thk Dia: 55 Dia
21.	Operating Panel	Make: BLPTPL Type: Non FLP, push button type



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

S.No.	Name of Component	Technical Specification
22.	Safety Valve At Steam Line	Make: Spirex MOC: Gun metal 15 B
23.	Electric Actuated Solenoid Valve At Steam Line	Make: Aira MOC: ½ “BSP Volt : 230 V AC
24.	Gate Valve At Steam Line	Make: HVI MOC: gun metal, ½ “ NB
25.	Gate Valve at condensate line	Make: HVI MOC: gun metal, ½ “ NB
26.	Steam Trap At Condensate Line	Make: HVI MOC: ½ “ NB



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material Of Construction	Reference
1.	Inside kettle	SS 316 L	GMP Requirement
2.	Outside kettle	SS 304	GMP Requirement
3.	Main Bowl	SS 316 L	GMP Requirement
4.	Jacket bowl & shell	SS 304	GMP Requirement
5.	Insulation Bowl & Shell	SS 304	GMP Requirement
6.	Stirrer	SS 316 L	GMP Requirement
7.	Mounting stand	SS 304	GMP Requirement
8.	Motor(0.50 HP)	STD	Process Requirement
9.	Gear box	STD	Process Requirement
10.	Gear motor guard	SS 304	GMP Requirement
11.	Handel for tilting	SS 304	GMP Requirement
12.	Control panel	SS 304	GMP Requirement
13.	Temp. sensor PT-100	STD	Process Requirement
14.	Pillow Bock Bearing	STD	Process Requirement
15.	Worm Gear With Worm Wheel	CI	Process Requirement
16.	Anchor Blade	SS 316 L	Process Requirement
17.	Anchor Shaft	SS 316 L	Process Requirement



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs	Safety Requirement
Metal Parts	All the metal parts should be Properly grind without any sharp edges.	Safety Requirement
Earthing	proper earthing is provided to the machine	
Leveling And Balancing	Equipment should be properly balanced & leveled	Safety Requirement
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Single external Earthing to control machine (panel and motors) and operator should be provided	Safety Requirement
Noise Level	Below 80 db averaged over source operative period. At distance of 1 mtr. From the noise source at a height of 1.5 mtr	Safety Requirement
Safety inter locks	All safety inter lock should be correctly incorporated as per the process flow and inter-linkages.	

8.0 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Observation	Reference
Selection of Vendor for supplying the Paste Kettle	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	selection of Vendor is done as per the procedure of Vendor Approval and all the relevant aspects including Vendor background, Technical knowhow, Quality standards, Inspection of site, costing, feedback from market considered prior to Vendor selection.	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement.

(2) Operation and service manual for Paste Kettle.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

12.0 RECOMMENDATION:

.....

.....

.....

.....

.....

.....

.....

.....



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

13.0 ABBREVIATIONS:

URS	:	User requirement specification
cGMP	:	Current Good Manufacturing Practice
cGEP	:	Current Good Engineering Practice
QA	:	Quality Assurance
PO	:	Purchase Order
Kg	:	Kilogram
Hr	:	Hour
mm	:	Millimeter
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
MCB	:	Miniature circuit breaker
db	:	Decibel
C.I.	:	Cast Iron
RH	:	Relative Humidity
MOC	:	Material of construction
NLT	:	Not less than
HP	:	Horse power
KW	:	Kilo watt
SS	:	Stainless steel
PLC	:	Programmable logical control
ID.	:	Identification
MCB	:	Miniature circuit break
HMI	:	Human machine interface
PAK	:	Paste Kettle



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR PASTE KETTLE

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			