DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
JACKETED MANUFACTURING TANK

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PROTOCOL CONTENTS

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT JACKETED MANUFACTURING TANK	PROTOCOL No.:

1.0 PROTOCOL 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)			

2.0 OBJECTIVE:

- To prepare the installation Qualification on basis of User Requirement Specification, Purchase Order and information given by Supplier.
- To ensure that all Critical Aspects of Equipment/Product Requirement, cGMP and Safety have been considered in designing the Equipment and is properly documented.
- To specify the performance basis for acceptance of equipment.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for jacketed MFG tank (1000 ltr.) module procured.
- The Equipment shall operate under the Controlled Environmental Conditions as per the cGMP requirements.
- The drawings and P & ID’s provided by Vendor shall be verified during Design Qualification.

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	• Preparation, Review and Approval of the Protocol cum Report. • Protocol Training. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification activity. • Review of Design Qualification cum Report Protocol after Execution.
Production	• Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameter, Drawings, as per the Specification. • Review of Design Qualification cum Report Protocol after Execution.

Engineering	• Review of Design Qualification 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.
	  • 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
	  • Brief Equipment Description
	  • Safety Features and Alarms
	• Review of Design Qualification cum Report Protocol after Execution.

5.0 PROJECT REQUIREMENTS:

To confirm the safe delivery of the Equipment from the supplier Site. To ensure that no Unauthorized and / or Unrecorded design modification shall take place. If at any point in time, any change is desired in the mutually agreed design, Change Control procedure shall be followed and documented.

The Compounding Vessel, its associated components and stirrer are designed to process pharmaceutical Products in accordance with cGMP principles.

6.0 BRIEF EQUIPMENT DESCRIPTION:

Jacketed Mfg. tank and its components are designed to process pharmaceutical products in accordance with cGMP principles. Manufacturing Vessel is used for mixing of Pharmaceuticals product with bottom entry magnetic stirrer.

7.0 EQUIPMENT SPECIFICATION :

Equipment Specification is a document provided to Manufacturer for Engineering Equipment as per the specifications mentioned in User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 PROCESS / PRODUCT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: The purpose of manufacturing vessel is mixing of pharmaceutical product with magnetic stirrer.	Manufacturing vessel shall be • Able to dissolve the Solid content in the Solvent Media to provide solution • Leak free • Jacketed to control the temperature of the solution	Process Requirement
Working	Should work smoothly and should run without producing any unwanted sound.	Process Requirement

8.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY :

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	415 Volts AC , 50 Hz & 3 phase	Design Requirement
Room Condition	Should be able to meet the requirement of Clean Environment.	cGMP Requirement
Steam	2-2.5 kg/cm^2	Process Requirement
Compressed Air Supply	5-6 kg/cm^2	Process Requirement
Service Water	20 BSP line at 2 kg/cm^2	Process Requirement
Cooling Water	40 BSP Header at 100 lt./Hr	Process Requirement

8.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES

MANUFACTURING VESSEL:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Gross Capacity	1000 Ltr.	Design Requirement
Working Capacity	750 Ltr.	Design Requirement
Minimum Capacity	60 Ltr.	Design Requirement
Shell	5 mm Thick SS 316 L	Design Requirement
Bottom	6 mm Thick AISI 316 L with type	Design Requirement
Propeller Type Stirrer	SS316 RPM max.960.	
Discharge Valve	Manual Ball Valve	
Lid	SS304	Design Requirement
Jacket	5 mm , SS 304 with spiral type Stiffeners	Design Requirement
Insulation	40 mm Thick Armaflex HT with SS304 Cladding 14 SWG Sheet welding type	Design Requirement
Legs	SS 304, 100 NB Dia x 40 SCH Pipe leg 3 Nos.	Design Requirement
Cladding	Made of 2 mm thk SS 304	Design Requirement
Safety Valve	Make: Inoxpa Set Pressure +3 kg/cm²	Safety Requirement
VFD	Type : V20 Model : 6SL 3210-5BE17-5UVO	Design Requirement
Vessel Connection on Top Dish-end		
Steam Inlet/ Cooling Outlet	25mm dia. with manual operated ball valve	Process Requirement
Condensate inlet /Cooling inlet	25mm dia. with manual operated ball valve	Process Requirement
Vessel Working Pressure		
Temperature	25-100°C	Design Requirement
Jacket Working Pressure		
Temperature	25-100°C	Design Requirement

8.4 MATERIAL OF CONSTRUCTION

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION
1.	Vessel shell	SS316L
2.	Jacket shell	SS 304
3.	legs	SS 304
4.	Lid	SS 304
5.	Insulation	SS 304
6.	Safety valve	SS 304
7.	Pressure gauge for jacket	SS304
8.	Manual Ball Valve	SS304
9.	Contact part	SS316 L
10.	Non Contact part	SS304

8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Electrical Wiring and Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine, Panel and operator should be provided	Safety Requirement
Noise Level	Below 80 db	Safety Requirement
Operation	Manufacturing vessel should be in working condition, and it should be repeated during shutting also.	Safety Requirement
Variable Frequency Drive	Motor safety from overload	Safety Requirement
Main Supply	Main power supply should be always switched off when not in use.	Safety Requirement
Safety valve	Safety against over pressure	Safety Requirement
Insulation	For operator safety & Heat loss prevention	Safety Requirement
Emergency Button	Protection against abnormal condition	Safety Requirement

8.6 VENDOR SELECTION:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Selection of Vendor for Manufacturing vessel.	Selection of Vendor is done on the basis of review of vendor. Criteria for review includes Vendor Background (General / Financial), Technical know -how, Quality Standards, Inspection of Site, Costing, feedback from Market.	cGMP Requirement

Reference: **(1)** The equipment shall confirm to the Specifications and Requirement as specified in URS.

(2) Operating and service manual for manufacturing vessel.

9.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the Supplier, if any.
- Purchase Order Copy
- Any other relevant Documents

10.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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11.0 ANY CHANGES MADE AGAINST THE FORMALLY AGREED PARAMETERS:

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12.0 RECOMMENDATION:

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13.0 ABBREVIATIONS:

AC	:	Alternate current
AISI	:	American Iron & Steel Institute
BSP	:	British Standard Pipe
cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate
db	:	Decible
DQ	:	Design Qualification
GA	:	General Arrangement
HP	:	Horse Power
Hz	:	Hertz
Kg	:	Kilograms
KW	:	Kilo Watt
Ltd.	:	limited
MFT	:	Manufacturing Vessel
mm	:	Millimeter
MOC	:	Material of Construction
PLC	:	Programmable Logic Controller
PO	:	Purchase Order
PVT.	:	Private
QA	:	Quality Assurance
SS	:	Stainless Steel
SS	:	Stainless Steel
Temp.	:	Temperature

14.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			