DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STIRRER

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

PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STIRRER	PROTOCOL No.:

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PHARMA DEVILS	DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR STIRRER	PROTOCOL No.:

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

2.0 OBJECTIVE:

- To prepare the Design Qualification document for Stirrer on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and are properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Stirrer (Make:** Om Fabricators**)**.
- The equipment shall be operated 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.

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 and authorization of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. • Post Approval of Design Qualification Protocol cum Report after Execution.
Production	• Review of Design Qualification Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Design Qualification Protocol cum Report after Execution
Engineering	• Review of Design Qualification Protocol cum Report. • Assist in the Preparation of the Protocol cum Report. • 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 ➢ Material of construction of all components ➢ Brief Process Description ➢ Safety Features and Alarm • Post Approval of Design Qualification Protocol cum Report after Execution

5.0 BRIEF EQUIPMENT DESCRIPTION:

Stirrer is suitable for emulsifying, dispersing, mixing and comminuting of liquid to Liquid products. It is based on rotor- stator principle. It is available in plain as well as water jacketed model which are suitable for heat sensitive products.

Special design facilitates adjustment of the grinding gap by an exterior screw by means of handle even during operation.

Stirring is an important step in pharmaceutical manufacturing process.

Operation:

Product is fed to the operating area of a rotor, having a speed of 500 RPM by specially designed feed device. The product is processed by high shear, pressure & friction between two Phases, and also, which exerts their force on it by means of pressing & releasing action.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared for the manufacturer of equipment ensures complies with User Requirement Specification.

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS / PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Application: The Stirrer should be able to mix various products.	Stirrer should meet the requirement.	Process Requirement
Working: Working of Stirrer	Stirrer should be capable of mixing of pharmaceuticals ingredients.	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

7.2 UTILITIY REQUIREMENTS / LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply	KW/HP : 2.2/3 Supply : 415 V, 3 Phase AC, 50 Hz	cGMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
Equipment	Stirrer (Om Fabricators)	Design Requirement
Model No.	GMP	Design Requirement
Capacity	Std	Design Requirement
Main Motor	Make : Hindustan Motor speed : 500 RPM (±10%) Supply : 415 V,3Phase AC,50 Hz Type : Flange mounted, TEFC Frame : 90 L KW/HP : 3 kw/	Design Requirement
FLP Starter	Make : FCG Hp : 3 Relay : 4 to 6 amp	Design Requirement
Castor Wheel	Make : Swift Size : ø65 x 25mm Model : SSPU6525M	Design Requirement
Application	Stirrer is Suitable for Emulsifying, Dispersing, and Mixing Comminuting of Liquids to Liquid.	Process Requirement
Temperature Controller	TC513	Process Requirement
Sensor	PT100	Process Requirement
RPM	(10-500)rpm	Process Requirement

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material Of Construction
1.	Rotor	SS316
2.	Cap On Rotor	SS316
3.	Center Bolt	SS316
4.	Stator	SS316
5.	Body Cover	SS304
6.	Top Cover	SS304
7.	Motor Housing	C.I.
8.	Baffle	SS316
9.	Base For Housing	CI

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 grounded without any sharp Edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
Electrical Wiring And Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine (panel and motors) and operator should be provided.	Safety Requirement
Noise Level	Below 80 db.	Safety Requirement
Emergency Switch	Provided easy access position.	Safety Requirement

7.6 VENDOR SELECTION:

Critical Variables	Acceptance Criteria	Reference
Selection of Vendor for supplying the Stirrer.	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)	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement as specified in PO and **URS**.

(2) Operating and service manual for Srirrer.

8.0 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

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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	current Good Manufacturing Practices
EU	:	European Union
SS	:	Stainless Steel
QA	:	Quality Assurance
IQ	:	Installation Qualification
SOP	:	Standard Operating Procedure
QA	:	Quality Assurance
mm	:	Millimetre
Hz	:	Hertz
V	:	Volt
No.	:	Number
URS	:	User Requirements Specification

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			