INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

STIRRER

EQUIPMENT ID. No.	
LOCATION	**Solution Preparation Room**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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

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

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)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Stirrer.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier

3.0 SCOPE:

- The Scope of Qualification Document is limited to the Installation Qualification of **Stirrer (Make: …….)** to be installed in **Solution Preparation Room**, **Coating area**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.

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	• Initiation, Review, Approval, Authorization, and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Stirrer Installation Qualification Activity. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Stirrer
Equipment ID.	
Manufacturer's Name	Techmach Engineering Works.
Model .No	GMP
Supplier's Name	Techmach Engineering Works.
Location of Installation	Solution Preparation Room

6.0 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.

Three way cock system for drainage & recirculation of liquids provided as standard. Extra discharge spout provided as a standard for viscous products.

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

Stirrer is an important step in pharmaceutical manufacturing process; this equipment is a self Contained & portable unit for the process of size reduction. It uses the principle of impact of air. The product is dropped axially from the hopper in a communication chamber where it comes in contact with blades rotating at high speed.

Operation:

Product is fed to the operating area of a rotor, having a speed of 2800 RPM by specially designed feed device. The product is processed by high shear, pressure & friction between two Phase, and also, which exerts their force on it by means of pressing & releasing action..

7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved design qualification document
- Piping and instrumentation diagram (P& ID)
- Technical specification of equipment
- Certificate of material of construction of components.

7.1.1 Procedure:

- Verify the above mentioned documents for availability, completeness and approval status
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum report.

7.1.2 Acceptance Criteria:

- All the documents should be available, complete and approved by respective authorities.

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

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Installation Qualification Checklist:

S.No.	Installation Check	Observation	Observed by (Engineering) Sign/ Date
1.	Check for the Dimensional accuracy		
2.	Check for the receipt of the consignment in good condition		
3.	Check for any scratches on the machine body		
4.	Check for the electrical panel. All Electrical connections should be as per the Circuit Diagram.		
5.	Check the Rotor Assembly Free Movements		
6.	Check The Grease in the Bearing Housing		
7.	Check the Direction of Rotation		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.2 Technical specification:

S.No.	Component	Location	Observation	Observed by Engineering (Sign/Date)
1.	Model.No	GMP		
2.	Capacity	Std		
3.	Main Motor	Make : Hindustan Motor speed : 2800 RPM (±10%) Supply : 415 ,3Phase, 50 Hz Type : Flange mounted, TEFC Frame : 90 L KW/HP : 2.25/3		
4.	FLP Starter	Make : FCG HP : 3 Relay : 4 to 6 amp		
5.	Castor Wheel	Make : Swift Size : 65 x 25mm Model : SSPU6525M		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.3 MOC Verification List:

S.No.	Component	MOC	Observation	Observed by Engineering (Sign/Date)
1.	Rotor	SS316		
2.	Cap On Rotor	SS316		
3.	Center Bolt	SS316		
4.	Upper Stator	SS316		
5.	Lower Stator	SS316		
6.	Baffle	SS316		
7.	Body Cover	SS304		
8.	Top Cover	SS304		
9.	Motor Housing	CI		
10.	Base For Housing	CI		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.4 SAFETY:

Critical variables	Acceptance criteria	Observation	Observed by Engineering (Sign/Date)
Mechanical Guard	Mechanical guard for all rotating parts.		
Joints	Welding of joints without any welding burrs.		
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.		
Leveling and Balancing	Equipment should be properly balanced & leveled.		
Electrical Wiring	Electrical wiring should be as per approved drawings.		
Noise Level	Below 80 db.		
Emergency Switch	Provided easy access position.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……..

9.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

AC	:	Alternative Current
cGMP	:	current Good Manufacturing Practices
DQ	:	Design Qualification
Hz	:	Hertz
IQ	:	Installation Qualification
Ltd	:	Limited
mm	:	Millimetre
MOC	:	Material of Construction
No.	:	Number
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
SRR	:	Stirrer
Std	:	Standard
V	:	Volt
WHO	:	World Health Organization

17.0 POST- 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)			