



**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
STIRRER**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
STIRRER**

<b>EQUIPMENT ID. No.</b>	
<b>LOCATION</b>	<b>LIQUID LINE</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



PHARMA DEVILS

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
STIRRER**

**PROTOCOL No.:**

**CONTENTS**

<b>S.No.</b>	<b>TITLE</b>	<b>PAGE No.</b>
<b>1.0</b>	<b>Pre-Approval</b>	<b>3</b>
<b>2.0</b>	<b>Objective</b>	<b>4</b>
<b>3.0</b>	<b>Scope</b>	<b>4</b>
<b>4.0</b>	<b>Responsibility</b>	<b>5</b>
<b>5.0</b>	<b>Equipment Details</b>	<b>6</b>
<b>6.0</b>	<b>Equipment Description</b>	<b>6</b>
<b>7.0</b>	<b>Pre-Qualification Requirements</b>	<b>7</b>
<b>8.0</b>	<b>Critical Variables to be Met</b>	<b>8-11</b>
<b>9.0</b>	<b>References</b>	<b>12</b>
<b>10.0</b>	<b>Documents to be Attached</b>	<b>12</b>
<b>11.0</b>	<b>Deviation from Pre-Defined Specification, If Any</b>	<b>13</b>
<b>12.0</b>	<b>Change Control, If Any</b>	<b>13</b>
<b>13.0</b>	<b>Review (Inclusive of follow up action, If Any)</b>	<b>13</b>
<b>14.0</b>	<b>Conclusion</b>	<b>14</b>
<b>15.0</b>	<b>Recommendation</b>	<b>14</b>
<b>16.0</b>	<b>Abbreviations</b>	<b>15</b>
<b>17.0</b>	<b>Post Approval</b>	<b>16</b>



**PHARMA DEVILS**

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
STIRRER**

**PROTOCOL No.:**

**1.0 PRE – APPROVAL:**

**PREPARED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OFFICER/EXECUTIVE (QUALITY ASSURANCE)</b>			

**REVIEWED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>OPERATING MANAGER (QUALITY ASSURANCE)</b>			
<b>HEAD (ENGINEERING)</b>			

**APPROVED BY:**

<b>DESIGNATION</b>	<b>NAME</b>	<b>SIGNATURE</b>	<b>DATE</b>
<b>HEAD (PRODUCTION)</b>			



PHARMA DEVILS

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
STIRRER**

**PROTOCOL No.:**

**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:**

- To verify the critical dimensions of the unit and record Serial Numbers / Model Number of critical Components.
- To verify that the correct hardware has been installed, system initializes correctly.
- To record the as-built drawing numbers of equipment drawing, P & ID and circuit diagram.



**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
STIRRER**

**PROTOCOL No.:**

**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
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation , Review, Authorization and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Installation Qualification.</li><li>• Monitoring of Installation Qualification Activity.</li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Installation Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Installation Qualification Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in Stirrer Installation Qualification Activity.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li><li>• Post Approval of Installation Qualification Protocol cum Report after Execution.</li></ul>



PHARMA DEVILS

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
STIRRER**

**PROTOCOL No.:**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Stirrer
<b>Equipment ID.</b>	
<b>Manufacturer's Name</b>	Om fabricators
<b>Model .No</b>	GMP
<b>Supplier's Name</b>	Om fabricators
<b>Location of Installation</b>	Liquid Line

**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.

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.

**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:** .....



PHARMA DEVILS

**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
STIRRER**

**PROTOCOL No.:**

**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 : 500 RPM (±10%) Supply : 415 V,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		
6.	Temperature Controller	TC513		
7.	Sensor	PT100		
8.	RPM	(0-500)rpm		

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....





PHARMA DEVILS

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PROTOCOL CUM REPORT  
FOR  
STIRRER**

**PROTOCOL No.:**

**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.	Stator	SS316		
5.	Body Cover	SS304		
6.	Top Cover	SS304		
7.	Motor Housing	C.I.		
8.	Baffle	SS316		
9.	Base For Housing	CI		
10.	Rotor	SS316		

**Checked By**  
**Production**  
**Sign/Date:** .....

**Verified By**  
**Quality Assurance**  
**Sign/Date:** .....

**Inference:**

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**Reviewed By**  
**Manager QA**  
**Sign/Date:** .....



PHARMA DEVILS

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PROTOCOL CUM REPORT  
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**PROTOCOL No.:**

**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:** .....



PHARMA DEVILS

**INSTALLATION QUALIFICATION  
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STIRRER**

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**9.0 REFERENCES:**

- Design Qualification Protocol cum Report
- GA Drawing
- Operating manual
- Wiring Diagram

**10.0 DOCUMENTS TO BE ATTACHED:**

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- P & ID

**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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PHARMA DEVILS

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**15.0 RECOMMENDATION:**

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**16.0 ABBREVIATIONS:**

- cGMP : current Good Manufacturing Practices
- DQ : Design Qualification
- Hz : Hertz
- IQ : Installation Qualification
- mm : Millimetre
- MOC : Material of Construction
- No. : Number
- QA : Quality Assurance
- QA : Quality Assurance
- SOP : Standard Operating Procedure
- V : Volt
- WHO : World Health Organization



PHARMA DEVILS

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**17.0 POST- 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)			