OPERATIONAL QUALIFICATION

PROTOCOL CUM REPORT

FOR

STIRRER

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

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

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PHARMA DEVILS	OPERATIONAL 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)			

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

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Stirrer and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features

3.0 SCOPE:

- The scope of this Operational Qualification protocol cum report is limited to Qualification of **Stirrer** installed in **Solution Preparation Room**.
- The Stirrer is a standalone unit with plug in type electrical connections for operation and is on castor wheel. Hence, may be moved as per requirement to other area of operation which shall not change the performance of equipment.
- This Protocol will define the methods and documentation used to perform OQ activity the Stirrer for OQ. Successful completion of this Protocol will verify that Stirrer meet all acceptance criteria and ready for Routine Use.

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

5.0 EQUIPMENT DETAILS:

Equipment Name	Stirrer
Equipment ID.	……..
Manufacturer's Name	Techmach Engineering Works
Model	GMP
Supplier's Name	Techmach Engineering Works
Location of Installation	Solution Preparation Room

6.0 EQUIPEMENT 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.

Stirrering is an important step in pharmaceutical manufacturing process.

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
- 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.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.

Any deviations or issues should be rectified and documented prior to OQ commencing

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	Draft SOP for operation & Cleaning of Stirrer			
4.	Draft SOP for Preventive Maintenance of Stirrer			

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.2 Test Equipment Calibration:

Verify that all critical instruments associated with the system will be in a calibrated state. Review the calibration status for the test equipment to be utilised and record the calibration due dates in the table below. All Equipment / Instrumentation must remain within the calibration due date for the duration of OQ test for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it can be utilised.

Equipment / Instruments Name	Equipment / Instrument ID	Calibration On	Due On	Observed By Sign/Date

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.3 Operational And Functional Checks:

Operate the Stirrer as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Item	Acceptance criteria	Observation	Observed By (Engineering) Sign/Date
Power supply	Connect 3Ph, 415V, AC supply to the control panel through proper isolator		
Motor & drive	Check the direction of motor shows on machine by direct arrow.		
ON-OFF Operation Push Button	Green Button Operation Starts & Red Operation Stops as Required		
Blades	Check that blades should be properly tightened.		
Application	Stirrer is Suitable for, Mixing Comminuting of Liquids to Liquid.		

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 Testing / Interlocking:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
To deactivate the equipment in event	The machine should stop immediately and should not start when started till emergency stop switch is released		
Off an emergency Stop	The machine should be made to turn off during any emergency.		
Noise Level	Below 80 db		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.5 Power Failure Verification:

Item	Acceptance Criteria	Observation	Observed By (Engineering) Sign/Date
Main Power Shut Down	Equipment stops in a safe and secure condition.		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

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:

- Operation And Maintenance Manual
- Copy Of Draft SOPs
- Any Other Relevant Documents

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:

cGMP	:	Current Good Manufacturing Practices
CQA	:	Corporate quality assurance
DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
Ltd	:	Limited
mm	:	Millimetre
MOC	:	Material of construction
NLT	:	Not less than
No.	:	Number
OQ	:	Operational Qualification
Pvt	:	Private
QA	:	Quality Assurance
SRR	:	Stirrer
SS	:	Stainless steel
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)			