



**INSTALLATION QUALIFICATION
PROTOCOL CUM REPORT
FOR
OCTAGONAL BLENDER
(CAPACITY- 1250 LITERS)**

EQUIPMENT ID. No.	
LOCATION	
DATE OF QUALIFICATION	
UPERSEDE PROTOCOL No.	NIL



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

PROTOCOL CONTENTS

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

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)			



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2.0 OBJECTIVE:

- To carry out the Installation Qualification of Octagonal Blender to be used for mixing of powder or blends and granulating the materials in formulation Plant.
- To confirm that the equipment and its components are as per the Specifications and Installed as per the Approved Design and complies with cGMP practices.
- To ensure that there is sufficient information available to operate and maintain the equipment Safely, Effectively and Consistently.

3.0 SCOPE:

- The scope of this installation qualification protocol cum report is limited to installation qualification of **Octagonal Blender (Make-Elicon Pharma, Capacity- 1250 liter)** to be installed in the Granulation.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required for installation qualification activity.



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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	<ul style="list-style-type: none">• Initiation, Review, Approval 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 Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Protocol cum Report.• Co-ordination, Execution and technical support in Octagonal Blender Installation Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Qualification Protocol cum Report after Execution.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Octagonal Blender
Equipment	
Manufacturer's Name	Elicon Pharma
Model	GMP Model
Serial No.	EP/PCHPL/OGB-1250/SEPT/2015
Supplier's Name	Elicon Pharma
Location of Installation	Granulation

6.0 SYSTEM DESCRIPTION:

Octagonal blender is a single drive mixing unit. It consists of SS central portion with a baffle arrangement, top frustum is provided with rectangular opening for cleaning, bottom conical frustum is provided with rectangular opening for cleaning, bottom conical frustum is provided with a circular opening provided for discharge. Complete body is supported with the hollow driving shaft with sprocket and chain drive mechanism which are supported on Plummer blocks at both ends.

Octagonal blender units are stand-alone and modular. The discharge of the blender is through pneumatically actuated butterfly valve. Mounting on tabular frame works covered with S.S. panels. Motor and gear box is mounted on platform fixed to a structure.

The major components of the octagonal blender are:

- Blender Body
- Main Hole for Charging
- Discharge with Pneumatic Actuated Valve
- Drive Mechanism
- Machine Base
- Main Control Panel
- Operating Panel
- Guard Rail

Blender body:

Octagonal blender is a single drive, mixing unit. It consist of SS central portion with a baffle arrangement, top frustum is provided with rectangular opening with a lid and a gasket which is tighten with no. of wings nuts bottom conical frustum is provided with a circular flanged opening to mount



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manual valve for cleaning/discharge. Shaft rest on Plummer blocks with self aligning or ball bearing mounted on adapter sleeves. Lock nut with sleeves ensures proper bearing loading onto the shaft.

Main Hole for Charging:

Suitable rectangular opening with SS lid and gasket is provided for charging the material in blender. Lid is lockable with wing nut and bolts to avoid spillage during the blending.

Discharge with Pneumatic Actuated Valve:

The discharge of the blended material is through pneumatically actuated butterfly valve.

Drive Mechanism:

The drive mechanism is provided with motor directly coupled with gear box. Output from the gear reducer engages the sprocket fitted on driving shaft on the blender body through chain drive. Shaft runs through a self – aligning pillow type-bearing block. Shaft either directly welded to the body of the blender or offered at a flange connection for ease of alignment. Drive shafts on opposite end are similarly supported on pillow units, thereby giving smooth rotary motion. A hand wheel is provided on the fan end of the motor to facilitate the discharge by indexing in a position for removing the material without much effort, when it has to be brought to rest in the discharge position.

Machine Base:

Tubular support frame, 'A' profiled at both ends of the body. Support designed to achieve wide base for distribution of the turning mass load and moment. Two section tied together with a cross member at the rear. Top of the stand truncated with pad plate for mounting the pillow blocks. Guardrails fixed at the front and the rear of the stand.

Main Panel:

It consist of the entire master electrical control pre- wired with suitable interlocks/overload protectors, fuses, MCBs, isolator switches etc. the main electrical phase supply is connected into this panel.

Operating Panel:

An operating panel is mounted on the frame of the blender. It consists of all the necessary push buttons for the various operational features of the blender.

Guard Rail:

Mechanical rail provided on the unit. Gate footprint to suit the turning radius of the blender body front set of railing in two sections open able, with limit switch/safety switch interlock rear set fixed, to prevent accidental intrusion into the blender rotational area.



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7.0 PRE-QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents :

- Executed and approved design qualification document.
- GA Drawing.
- Electrical Circuits Diagram.
- 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.



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8.0 CRITICAL VARIABLES TO BE MET:

8.1 Mechanical Installation Checklist:

S.No.	INSTALLATION CHECK	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	The machine has been positioned as per the room layout drawing.		
2.	The machine has been levelled.		
3.	The machine has been cleaned.		
4.	Utilities has been properly connected.		
5.	Visually check the machine for damage due to transportation.		

**Checked By
(Production)**
Sign/Date:

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

Inference:

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



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8.2 Electrical Installation Checklist:

S.No.	INSTALLATION CHECK	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Electrical connection have been provided and secured.		
2.	All components in the panel are properly secured.		
3.	All terminals are tightened.		
4.	Check incoming voltage/frequency.		
5.	Earthing connection to control panel & equipment.		

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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

8.3 General Checks and Location Suitability:

S.No.	INSTALLATION CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Grouting and Mounting	Should be grouted and mounted properly.		
2.	Edges of Parts.	Metal edges should be properly Rounded off without any sharp edges.		
3.	Welding of Joints	Welding of joints should be without any welding burrs.		
4.	Place of Installation	Granulation area		
5.	Room Condition	General working condition As per GMP and production requirement.		
6.	Illumination in area	NLT 300 Lux.		
7.	Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance.		

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Sign/Date:



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

8.4 Equipment Verification:

INSTALLATION CHECKS	SPECIFICATION	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Equipment	Octagonal blender.		
Model No.	GMP Model.		
Capacity	1250 Liters.		

ELECTRICAL INSTALLATION:

Electricity	Voltage	415 V		
	Phases	3 Phase		
	Frequency	50 ± 5%		
Proximity switch	Protecting the operator from machine while running.			
Baffle	For proper mixing of materials.			
Rectangular man hole	Tightened the wing nut properly after the material has been added.			
Butterfly valve	For discharging of the final product by opening the valve.			
Conical cover	For clamping the loading/unlading drum.			

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Sign/Date:

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Reviewed By (Manager QA)
Sign/Date:



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8.5 MOC Verification List:

S.No.	COMPONENT	MOC	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Octagonal shell	AISI316		
2.	Baffles	AISI316		
3.	Rectangular Manhole	AISI316		
4.	Butterfly Valve (6")	AISI316		
5.	S.S Square pipe railing	AISI304		
6.	Pipe for Motor and Gear Box mounting	AISI304		
7.	Plummer Block	STD		
8.	Gasket	White Silicon Food Grade		
9.	Motor	STD		
10.	Gear box	STD		
11.	VFD	STD		
12.	Process timer	STD		
13.	RPM indicator	STD		
14.	Control panel	AISI304		
15.	Proximity switch	STD		
16.	Handel for butterfly valve	AISI304		
17.	PLC	STD		
18.	HMI (TS1070)	STD		
19.	Amp Meter (MA-12)	STD		

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Sign/Date:



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

8.6 Equipment Verification:

8.5.1 Technical Specifications:

S. No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
1.	Equipment	Octagonal blender		
2.	Model No.	GMP Model.		
3.	Sr. No.	EP/PCHPL/OGB- 1250/SEPT/2015		
4.	Overall Dimension (in mm)	Length : 2600 Width : 2150 Height : 2300		
5.	Capacity	1250 Liters.		
6.	Net Weight	900 Kg		
7.	Blender RPM	6 to 12 RPM		
8.	Motor	Make : "REMI" HP : 5 HP Volt : 415 RPM : 1435 AMP : 7.1		
9.	Gear Box	Make : "Premium" Type : U 500 Ratio : 50/1 L Sr. No. : 7 B 34434		
10.	VFD	MAKE : "ABB" Type : ACS-550-01-08A8-4 Hp : 5 HP Sr. No. : 9140801116		
11.	Proximity Switch	Make : "HI-TECH" Model : NO Vol : 90V-250VAC		



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

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S. No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
12.	Process timer	Make : "SELEC" Size : 50 x 50 mm		
13.	PLC	Make : "MITSUBISHI" Type : FX3S-14M		
14.	HMI	Make : "Monitouch - Hakko Electronics co.ltd. Input : 24 VDC Current : 0.8A Size : 190 x 135 Sr. No. : 131000485		
15.	RPM Meter	Make : "SELEC" Model : PIC-101 Size : 96 x 48		
16.	AMP Meter	Make : "SELEC" Model : MA-12 Size : 96 x 48		
17.	Discharge Valve	Butterfly valve Inner dia. : 250 mm ID		

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Sign/Date:

Verified By
(Quality Assurance)
Sign/Date:

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Reviewed By
(Manager QA)
Sign/Date:



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

8.7 Safety:

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY ENGINEERING SIGN/DATE
Well embedded equipment	For octagonal blender machine		
Electrical wiring and Earthing	Electrical wiring should be as per approved drawings. Double external earthing to control machine panel and motors should be provided.		
Guards	Guards for all moving parts		
Safety	Should be provided For Motor safety		
Start On/Off switch: To stop the process immediately	Should be provided For equipment and operator safety		
Alarm/automatic system	Should have alarm and automatic system		

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Sign/Date:

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Sign/Date:

Inference:
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Reviewed By (Manager QA)
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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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INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

16.0 ABBREVIATIONS:

Amp	:	Ampere
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
GB	:	General Block
IQ	:	Installation Qualification
MCB	:	Miniature Circuit Break
mm	:	Millimetre
MOC	:	Material of construction
No.	:	Number
OBL	:	Octagonal Blender
RPM	:	Revolutions per Minute
Sr.	:	Senior
SS	:	Stainless Steel
STD	:	Standard
WHO	:	World Health Organization



INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

17.0 PROTOCOL 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)			