



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

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



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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

OPERATIONAL 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 verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and comply with cGMP Requirements.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To verify the operational features of Octagonal Blender and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user friendly point of view of the Machine, Cleaning Procedure and 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 **Octagonal Blender (Make- Elicon, Capacity- 1250 Liter)** to be installed in the **Granulation.....**
- This Protocol will define the methods and documentation used to perform OQ activity the Octagonal Blender for OQ. Successful completion of this Protocol will verify that Octagonal Blender meet all acceptance criteria and ready for Performance Qualification.



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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 Operation Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Operation Qualification.• Monitoring of Operation Process.• Post Approval of Operational Qualification Protocol cum after Execution.
Production	<ul style="list-style-type: none">• 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 after Execution.
Engineering	<ul style="list-style-type: none">• Review of Operational Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Octagonal Blender Operational Qualification Activity.• Calibration of Process Instruments.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Operational Qualification Protocol cum after Execution.



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5.0 EQUIPMENT DETAILS:

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

6.0 EQUIPEMENT 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 s 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.
- Calibration Certificate 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 OQ 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 Documents Verification:

S. No.	DOCUMENT NAME	DOCUMENT/SOP No.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING SIGN/DATE)	VERIFIED BY (QA) SIGN/DATE
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	Draft SOP for Operation & Cleaning of Octagonal Blender				
4.	Draft SOP for Preventive Maintenance of Octagonal Blender				

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 Operational and Functional checks:

Operate the Octagonal blender machine 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, 415 v, AC supply to the control panel through proper isolation		
Motor gear box and AC drive	Check direction of motor shows on machine by direction arrow		
	Gear box transmit the speed to machine from motor.		
	AC drive transmits the power form gearbox to the body of the blender for rotating.		
Earthing	Proper earthing should be provided to machine		
Proximity switch	Protecting the operator form machine while machine is in operation.		
Rectangular manhole	Should be tight properly without any leakage.		
Butterfly valve	Should be open and close smoothly.		
Conical cover	For clamping the loading/unloading drum.		
VFD	Provided to get different RPM of blender (One pot is provided on control panel to change the RPM of blender)		
RPM Meter	Provided on Control Panel to see the actual RPM of Blender		

Checked By (Production)

Sign/Date:

Verified By

(Quality Assurance)

Sign/Date:

Inference:

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Reviewed By

(Manager QA)

Sign/Date:



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

8.3 Safety testing/interlocking:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Electrical Wiring And Earthing	Must be inside the machine		
Motor Overload Relay	The switchgear shall trip if overloaded		
Emergency Off	To stop the process immediately		
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: _____



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8.4 Operational & Functional check: Operational & Functional Check of octagonal blender during Power Failure Condition no disturbance take place on timer Setting and Equipment Stop & Run in a Safe and Securely .

PARAMETER		OBSERVATION/RESULTS		
		Trial-1	Trial-2	Trial-3
Set time duration	Initial Setting Time (A)			
Elapsed time values	Power failure at Time (B)			
	Remains Run time(C=A-B)			
	Total Run Time Before Power Failure (D=C-A)			
	After Power Incoming Equipment Run (E=A-D)			
	Total Run Time F=A			
	Power failure duration (H)			
	Total time duration on stop watch (G)			

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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8.5 Emergency Operation Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Emergency Stop • Press Emergency Stop Push Button.	Equipment should stop.		
• Release Emergency Stop Push Button.	Equipment should start.		
With the Emergency Stop Pressed in, try to cause movement of an Operating function.	The Equipment will be inoperative.		

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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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.
- Calibration certificates.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PREDEFINED 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
db	:	Decibel
DQ	:	Design Qualification
ID	:	Identification
IQ	:	Installation Qualification
MOC	:	Material of Construction
No.	:	Number
OBL	:	Octagonal Blender
OQ	:	Operational Qualification
SS	:	Stainless steel
WHO	:	World Health Organization



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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)			