PERFORMANCE QUALIFICATION

PROTOCOL

FOR

OCTAGONAL BLENDER

(CAPACITY- 1250 LITERS)

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

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PERFORMANCE QUALIFICATION PROTOCOL FOR OCTAGONAL BLENDER

1.0 PROTOCOL 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 provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operation Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the Octagonal Blender **(Make - Elicon Pharma, Capacity - 1250 liter)** installed in Granulation…….
- This Protocol will define the methods and documentation used to qualify the Octagonal Blender for PQ.

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 and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Review of Performance Qualification Protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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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.	EP/PCHPL/OGB-1250/SEPT/2015
Supplier's Name	Elicon Pharma
Location of Installation	Granulation

6.0 EQUIPMENT 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**
- **Man hole for discharging**
- **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 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.

Man Hole:

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:

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 REASON FOR QUALIFICATION:

- New equipment in Granulation.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Granulation.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two year.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- SOP for Operation & Cleaning of Octagonal Blender.
- SOP for Preventive Maintenance Octagonal Blender.

11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Octagonal blender.
- SOP for Preventive Maintenance Octagonal blender.

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.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

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

11.2 Evaluation of Performance Using Placebo Formulation:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish the performance based range of operating parameters for performance qualification activity using placebo formulation.

11.2.1 Checks:

- Product discharge function (Discharge should be efficient).
- Blending Efficiency (Increase in Untapped Density).

11.2.2 Method:

- Load the materials to the Octagonal Blender.
- Perform Mixing for 01 min.
- Collect samples from Upper, Middle & Lower location of Blender.
- Perform mixing for 15 min.
- Collect samples from Upper, Middle & Lower location of Blender.
- Test the collected samples of for Untapped Density, Tapped Density and Angle of Repose.
- Record the observations in the report.

11.2.3 Acceptance Criteria:

- Product discharge function should be efficient.
- On mixing untapped density of the samples should be increased.

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11.3 Evaluation of Performance Using Drug Products:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish documented evidence that the Octagonal Blender is performing consistently and the result of all test parameters meet the pre - defined acceptance criteria of Blended products.

11.3.1 Checks:

- Blend Uniformity Analysis for Assay.
- Blend Uniformity Analysis for Physical Parameters.

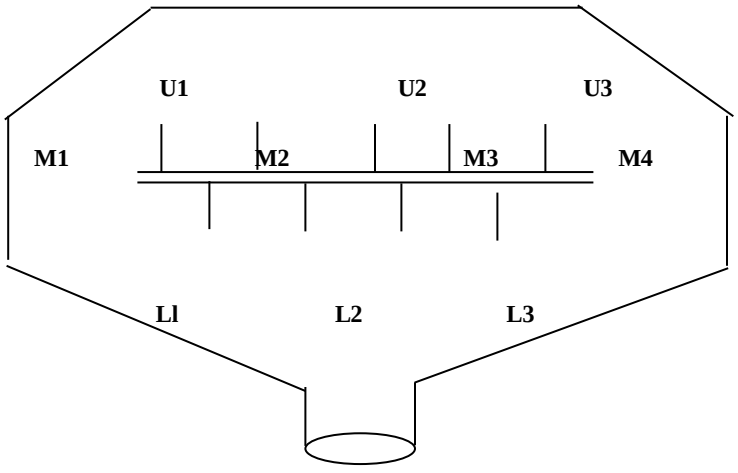
11.3.2 Method:

- The test shall be carried out on 3 batches of same or different products.
- Load the product to the Octagonal Blender.
- Perform Mixing for specified time mentioned in the BMR of products.
- Collect samples from 10 different locations of Blender and send to QC for analysis of % Assay (Blend Uniformity).
- Collect samples from Upper, Middle & Lower location of Blender (5 gm each) and send to QC analysis of physical parameters of blended granules (Untapped Density, Tapped Density and Angle of Repose).
- Record the observations in the report.

11.3.3 Acceptance Criteria:

- Result of Assay for each sampling location should meet the acceptance criteria given for each product.
- RSD of individual values of Assay of all sampling locations should not be more than 5.0%.
- Results of Physical Parameters for all sampling locations should not have a significant difference.

11.3.4 Sampling Locations:



OCTAGONAL BLENDER

Quantity of Sample: Each sample of 3 times average weight.

No. of Samples: 3 -Samples from Upper Layer
4 -Samples from Middle Layer
3 -Samples from Lower Layer
1- Composite sample

Where,

U1= Upper Left
U2= Upper Center
U3= Upper Right

L1= Lower Left
L2= Lower Center
L3= Lower Right

M1= Middle Left
M2= Middle Center 1
M3= Middle Center 2
M4= Middle Right

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance using Placebo Formulation.
- Verification of performance using Drug Products.

13.0 REFERENCES:

The Principle References are as 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.

14.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Raw Data of Analytical Testing.
- Any Other Relevant Documents.

15.0 NON COMPLIANCE:

- All the Non-compliances of procedure, specifications, sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
IQ	:	Installation Qualification
mm	:	Millimetre
No.	:	Number
OBL	:	Octagonal Blender
OQ	:	Operational Qualification
PQ	:	Performance Qualification
QA	:	Quality Assurance
RSD	:	Relative Standard Deviation
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization
GB	:	General Block