



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

DATE OF QUALIFICATION	
SUPERSEDE PROTOCOL No.	NIL



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	Protocol Pre-Approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Responsibility	5
5.0	Project Requirements	6
6.0	Brief Process Description	6-7
7.0	Equipment Specification	8
8.0	Critical Variables to be Met	8
8.1	Equipment Parameters	8
8.2	Utility Requirement / Location Suitability	8
8.3	Technical Specification /Key Design Features	9-11
8.4	Material of Construction	11
8.5	Safety	12
8.6	Vendor Selection	13
9.0	Documents to be Attached	13
10.0	Review (Inclusive of Follow Up Action, If Any)	13
11.0	Any Changes Made Against the Formally Agreed Parameters	14
12.0	Recommendation	14
13.0	Abbreviations	15
14.0	Reviewed By	16



DESIGN 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)			



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

2.0 OBJECTIVE:

- To prepare the Design Qualification on the basis of URS, Purchase Order and information given by Supplier.
- The purpose of Design qualification is to ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification for **Octagonal Blender (Make: Elicon Pharma, 1250 liter)** for
- The equipment shall operate under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & IDs provided by Vendor shall be verified during Design Qualification.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

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 and Approval of the Qualification Protocol cum Report• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.• Review of Qualification Protocol cum Report after Execution.
Production	<ul style="list-style-type: none">• Review of Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of Qualification Protocol cum Report• Assist in the Preparation of the Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing.➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/brochures.➤ Details of utilities Required.➤ Identification of components for calibration.➤ Material of construction of Product Contact Parts.➤ Brief Process Description.➤ Safety Features and Alarms.• Review of Qualification Protocol cum Report after Execution.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

5.0 PROJECT REQUIREMENTS:

To confirm that safe delivery of the equipment from the supplier site. To ensure that no un-authorized or unrecorded design modification shall take place.

If at any point in time, any change is desired in the mutually agreed design, change control procedure shall be followed and documented. The purpose of Octagonal Blender for rapid homogenizing/ blending of dry and semi dry powder /granules of pharmaceutical products.

6.0 BRIEF 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
- 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 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.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

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.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

7.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared by The manufacturer of equipment ensures complies with User Requirement Specification.

8.0 CRITICAL VARIABLES TO BE MET:

8.1 EQUIPMENT PARAMETERS:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Application: The Octagonal Blender should be able to mix various products.	Octagonal blender machine should meet the requirement for rapid homogenizing / blending of dry and semi dry products.	Process Requirement
Working: Working of Octagonal Blender	Octagonal Blender machine should be capable of vigorous mixing of pharmaceuticals ingredients and is subjected to variable speed mixing using VFD (Variable Frequency Drive)	Process Requirement
Electrical Control Panel	The system should have Electrical Control Panel.	Design Requirement

8.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
Utility connections should be available as per the manufacturer's specification.		
Electrical Supply:	The electrical system of the equipment shall be housed as per the cGMP and cGEP standards, with adequate safety. Electrical panel and electro pneumatic panel is to be installed in service area.	GMP Requirement
Compress air supply	Should be Oil & Dust free.	GMP Requirement
Room Condition	Temperature and RH required as per requirement of product.	Process Requirement



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

8.3 TECHNICAL SPECIFICATIONS/KEY DESIGN FEATURES:

S.No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA
1.	Equipment	Octagonal blender
2.	Serial No.	EP/PCHPL/OGB-1250/SEPT/2015
3.	Model No.	GMP Model
4.	Overall Dimension (in mm)	Length : 2600 Width : 2150 Height : 2300
5.	Capacity	1250 Liters
6.	Net weight	900 Kg
7.	Gross weight	1300 Kg
8.	Blender RPM	6 to 12 RPM
9.	Main Motor	Make : "REMI" HP : 5 HP Volt : 415 RPM : 1430 AMP : 7.1 Sr : 15/06/D626 Amp : 7.3 Type : FOOT MOUNTED Frame : 112M B/4R
10.	Gear Box	Make : "Premium Greaves" Type : U 500 Ratio : 50/1 L Sr. No. : 7 B57289
11.	VFD	MAKE : "ABB" Type : ACS-550-01-08A8-4 Hp : 5 HP Sr. No. : S144290085
12.	Proximity switch For Safety Guard	Make : "HI-TECH" Model : (NO)



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

S.No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA
13.	Proximity switch For Right Position	Make : "HI-TECH" Model : (NO)
14.	Chain Sproket Drive	Teeth (Sproket on Shaft of Blender) : 70 Teeth (Sproket on Gear Box) : 28 Teeth (Idler) : 15 Chain : ¾" Duplex
15.	Pillow Block Bearing	Make : SKD Model : P212 Qty : 2 Nos
16.	Rotoseal	Make : AIRMAX Model : ASRSD-RH-06 Pressure : 10 Kg/cm ² Qty : 2 Nos
17.	Solenoid Valve	Make : Camozzi Model : 5/2 – Double acting Volt : 230 V
18.	Process Timer	Make : "SELEC" Model : XT546 Size : 50 x 50 mm
19.	PLC	Make : "MITSUBISHI" Type : FX3S-14M
20.	HMI	Make : "MONITOUCH- HAKKO Electronics co.ltd." Input : 24 VDC Current : 0.8A Size : 190 x 135 mm Sr. No. : 131000485
21.	RPM Meter	Make : "SELEC" Model : PIC-101 Size : 96 x 48



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR OCTAGONAL BLENDER

S.No.	CRITICAL VARIABLES	ACCEPTANCE CRITERIA
22.	AM Meter	Make : "SELEC" Model : MA-12 Size : 96 x 48
23.	Discharge valve	Butterfly valve Inner dia. : 250 mm ID

8.4 MATERIAL OF CONSTRUCTION:

S.No.	PARTS NAME	MATERIAL OF CONSTRUCTION	REFERENCE
1.	Octagonal shell	AISI316	GMP Requirement
2.	Baffles	AISI316	GMP Requirement
3.	Rectangular Manhole	AISI316	GMP Requirement
4.	Butterfly valve (10")	AISI316	GMP Requirement
5.	S.S Square pipe railing	AISI304	GMP Requirement
6.	Pipe for Motor and Gear Box mounting	AISI304	GMP Requirement
7.	Pillow Block Bearing	STD	Process Requirement
8.	Gasket	White Silicon Food Grade	GMP Requirement
9.	Motor	STD	Process Requirement
10.	Gear box	STD	Process Requirement
11.	VFD	STD	Process Requirement
12.	Process timer	STD	Process Requirement
13.	RPM indicator	STD	Process Requirement
14.	Control Panel	AISI304	GMP Requirement
15.	Proximity switch	STD	Process Requirement
16.	Handel for butterfly valve	AISI304	GMP Requirement
17.	PLC	STD	Process Requirement
18.	HMI	STD	Process Requirement
19.	Amp Meter	STD	Process Requirement



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8.5 SAFETY:

CRITICAL VARIABLES	ACCEPTANCE CRITERIA	REFERENCE
MCB	MCB is provided so that when there is an overload in current or any short circuit then the MCB trips.	Safety Requirement
Mechanical Guard	Mechanical guard for all rotating parts.	Safety Requirement
Joints	Welding of joints without any welding burrs.	Safety Requirement
Metal Parts	All the metal parts should be properly grounded without any sharp Edges.	Safety Requirement
Leveling and Balancing	Equipment should be properly balanced & leveled.	Safety Requirement
Electrical Wiring and Earthing	Electrical wiring should be as per approved drawings. Double external Earthing to control machine panel and motors and operator should be provided.	Safety Requirement
Noise Level	Below 80 db.	Safety Requirement
Emergency Switch	Provided at easy access position.	Safety Requirement



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13.0 ABBREVIATIONS:

Amp	:	Ampere
cGEP	:	Current Good Engineering Practice
cGMP	:	Current Good Manufacturing Practice
db	:	Decibel
GA	:	General Arrangement
GB	:	General Block
HP	:	Horse Power
kg	:	Kilogram
MCB	:	Miniature Circuit Break
mm	:	Millimeter
MOC	:	Material of Construction
OD	:	Oral Solid Dosage
P & ID	:	Piping and Instrumentation Diagram
PO	:	Purchase Order
RH	:	Relative Humidity
RPM	:	Revolution per Minute
SS	:	Stainless Steel
STD	:	Standard
URS	:	User requirement specification

14.0 REVIEWED BY:



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

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DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

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HEAD (QUALITY ASSURANCE)			