Pharmaceutical Guidelines

USER’S REQUIREMENT SPECIFICATION

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1.0 Introduction: The Octogonal Blender 500 litre is used for mixing of dry mass as per requirement.

2.0 Overview:

2.1 Intended use: The Octogonal Blender 500 litre will be used for mixing of dry mass as per the requirement.

2.2 Production Capacity: The capacity of the machine is to be: .................kg depending on speed and size of the tablets.

2.3 Space Availability: Allocated floor space for the machine is 5500 mm X 4500 mm and vertical clearance is 2500 mm.

2.4 Accuracy of instrumentation desired: Not Applicable

2.5 Cleaning requirements: Easy to clean

2.6 Equipment Specific Requirement

2.6.1 It should be designed to meet latest cGMP standards & should have low maintenance cost.

2.6.2 The Octogonal Blender 500 litre having rotating shell with baffles.

2.6.3 All contact parts should be made up of SS 316 quality, internally mirror & externally matt finished.

2.6.4 Octogonal Blender 500 litre should be provided having 30 to 100 revolutions per minute.

2.6.5 It should have same charging port & discharge port.

2.6.6 It should have blender shaft drive.

2.6.7 There should be a safety guard around blender.

3.0 Operational Requirements

3.1 Functional Requirements

3.1.1 Operation

3.1.1.1 Operation shall be safe from an operator point.

3.1.2 Control System Requirements

3.1.2.1 There should be an “ON”, “OFF”, “INCH” switch.

3.1.2.2 It should be flame proof.

3.1.3 Power failure / Recovery

3.1.3.1 In the event of a power failure, the system shall stop automatically and will require operator intervention to re-start.

3.1.4 Safety Requirements

3.1.4.1 MCB will be provided so that when there is an overload in current or any short circuit then the MCB trips.
3.1.4.2 There should be a sensor attached to safety guard.

3.1.4.3 Grounding: Proper earthing should be provided.

3.2 Environment: The Octogonal Blender 500 litre will be installed in an environment with a temperature range of NMT 25 °C & %RH of NMT 60%

3.3 Other requirements: M.O.C. – Non contact ports – MS cladded with S.S 304. All seals should be of food grade silicon or neoprene rubber

4.0 Compatibility and Support

4.1 Utilities: The supplier shall indicate the requirement of utilities to be provided by the user while submitting the design specification.

Base Utilities Worksheet:
Electricity: 3 phase, 415V +/-10%, AC 50 Hertz +/-2%
Uninterrupted Power Supply: Not required.
Other utility requirements shall be discussed as needed.

4.2 Availability: The Octogonal Blender 500 litre is intended to be operated: Regularly 2 shifts.

4.3 Procedural Document requirement:
Supplier has to provide, Detailed functional specification and Design Qualification protocols, Drawings, electrical circuit diagrams, Operation & Maintenance Manual, Warranty letter, List of Standard spares, List of change parts.

5.0 Glossary / Abbreviations:
- V - Volts
- NMT - Not more than
- MOC - Material of construction
- MS - Mild steel
- SS - Stainless steel
- MCB - Miniature Circuit Breaker

6.0 References: IN-HOUSE

7.0 Approval

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