



PHARMA DEVILS

**DESIGN QUALIFICATION PROTOCOL
FOR
FILLED CAPSULE SORTER WITH MINI CAPSULE SORTER**

PROTOCOL No.:

**DESIGN QUALIFICATION
PROTOCOL CUM REPORT
FOR
FILLED CAPSULE SORTER WITH
MINI CAPSULE SORTER**

| | |
|--------------------------------|------------|
| DATE OF QUALIFICATION | |
| SUPERSEDES PROTOCOL No. | NIL |



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1.0 PRE – APPROVAL:

PREPARED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|--|-------------|------------------|-------------|
| OFFICER/EXECUTIVE (QUALITY ASSURANCE) | | | |

REVIEWED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|--|-------------|------------------|-------------|
| OPERATING MANAGER (QUALITY ASSURANCE) | | | |
| HEAD (PRODUCTION) | | | |
| HEAD (ENGINEERING) | | | |

APPROVED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|-------------------------------------|-------------|------------------|-------------|
| HEAD (QUALITY ASSURANCE) | | | |



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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, GMP 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 Automatic Filled Capsule sorter with Mini capsule Sorter with GMP Model.
- The equipment shall operate under the dust free environment and conditions as per the GMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design 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, Authorization and Approval of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Review of Qualification Protocol cum Report after Execution. • Co-ordination with Production and Engineering to carryout Design Qualification. • Monitoring of Design Qualification Activity. |
| Production | <ul style="list-style-type: none"> • Review of the Protocol cum Report. • Assist in the verification of Critical Process Parameters, Drawings as per the Specification. • Post Approval of Qualification Protocol cum Report after Execution. |
| Engineering | <ul style="list-style-type: none"> • Review of the 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 after Execution. |



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5.0 BRIEF PROCESS DESCRIPTION:

The entire equipment comprises of the following units:

5.1 Mini Capsule Sorter Unit

- Mini capsule sorter used to sort opened capsule cap or body shells coming from the polishing machine by means of a vibratory system.
- Mini Capsule Sorter Unit consists of sorting plates having holes with respect to capsule body & cap size.
- The cap & body separated capsules will then further flow into the filled capsule sorter drum for sorting diametrically distorted capsules.

5.2 Filled Capsule Sorter Unit

- Filled Capsule Sorter Unit consists of sorter drum having holes as per the capsule size
- The filled capsule sorter unit works on the principle that diametrically damaged or cylindrically out capsules won't pass through the holes on the sorter drum and are collected in the separate bin.
- The drive to the sorter unit is by directly connected motor & gearbox.
- A variable frequency drive is provided to vary the RPM of the sorter drum.
- The electrical controls such as MCB, VFD, etc. are placed in the common SS control panel

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification. The manufacturer of equipment ensures complies with User Requirement Specification. This is Automatic capsule filling machine.



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7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

| Parameters | Acceptance Criteria | Reference |
|-----------------------------------|---|--------------------|
| Model | The equipment should be a GMP compliant model. | Design Requirement |
| Material of Construction | All contact part should be made up of SS 316L. Other non-contact component are of Aluminum | Design Requirement |
| Cleaning & Maintenance | Should be easily cleanable and maintainable | Design Requirement |
| Control System | Equipment to be controlled. | Design Requirement |
| Electrical System | The electrical system of the equipment to be housed as per the GMP & GEP slandered | Design Requirement |

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

| Critical Variables | Acceptance Criteria | Reference |
|--|--|-----------------|
| Utility connections should be available as per the manufacturer's specification. | | |
| Electrical Supply | 3 Phase Plus Earthing, 5 Wire Line Up To The Panel Board Terminal. Voltage.: 415 V Frequency.: 50 Hz (To be assured by Engineering Department) | GMP Requirement |
| Electrical Connections on Machine/Panel | 415V, 3 Phase, 50 Hz, | |
| Room Condition | Should be able to meet the requirement of clean environment. | |



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7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

| S.No. | Parameter | Specification |
|-------|--|--|
| 1. | Capacity / Output | 1,00,000 to 1,20,000 capsules / hr for powder & 80,000 to 1,00,000 Capsules / hr for pellets 60,000 to 80,000 Capsules / hr for tablets Depending up on the quality of capsules, characteristics of product filled in the capsules & the room condition. |
| 2. | Capsule size | Machine is suitable for Any size from '00' to '4', However, Size#0 & Size #3 change parts will be supplied, as ordered. |
| 3. | Adjustments | Variable Frequency Drive is provided for filled capsule sorter unit. |
| 4. | Surface Finish | Internal Product Contact Parts - Mirror Finish i.e. < 0.4 Ra External Zone - Matt Finish i.e. < 0.8 Ra |
| 5. | Mode of machine cleaning | Manually |
| 6. | Room temperature | NLT 20 deg C and NMT 25 deg C |
| 7. | Room humidity | NLT 45 %RH and NMT 55 %RH |
| 8. | Filled Capsule sorter motor | Make – Bonfiglioli , Model – BN63 B4 0.18Kw, 50Hz |
| 9. | Filled Capsule Sorter gearbox | Make – Bonfiglioli, Model – VF44F100P63B5B3 |
| | Packing Specifications | |
| 10. | Machine Dimensions (in mm) - Approx | As per GA Drawing |



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7.4 MATERIAL OF CONSTRUCTION:

| S. No. | Parts Name | Material of Construction |
|--------|----------------------------|--------------------------|
| 1. | Capsule guide plate | SS 316 |
| 2. | Tray cover assly | SS 316 |
| 3. | Acrylic plate | Acrylic |
| 4. | Aluminum plate | Aluminum |
| 5. | Aluminum Spacer | Aluminum |
| 6. | S.S. Plate | SS 316 |
| 7. | Tray | SS 316 |
| 8. | Chute linear to Rotary | SS 316 |
| 9. | Collection Box | SS 316 |
| 10. | Rejection Tray | SS 316 |
| 11. | Rotor cover | SS 316 |
| 12. | Sorter Tray Holding Ring | Aluminum |
| 13. | Sorting Tray mounting ring | Aluminum |
| 14. | Capsule sorter Tray | Aluminum |

7.5 PRODUCT SURFACE CONTACT AREAS:

| Sr. No. | Component | Surface Area (in sq. mm) |
|---------|----------------------------|--------------------------|
| 1. | Capsule guide plate | 26763.22 |
| 2. | Tray cover assly | 55664.68 |
| 3. | Acrylic plate | 133126.17 |
| 4. | Aluminum plate | 78868.58 |
| 5. | Aluminum Spacer | 21707.824 |
| 6. | S.S. Plate | 123782.83 |
| 7. | Tray | 139303.79 |
| 8. | Chute linear to Rotary | 20765.87 |
| 9. | Collection Box | 81362.26 |
| 10. | Rejection Tray | 37487.29 |
| 11. | Rotor cover | 35250.15 |
| 12. | Sorter Tray Holding Ring | 45724.31 |
| 13. | Sorting Tray mounting ring | 60033.84 |
| 14. | Capsule sorter Tray | 389621.04 |



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7.6 MAJOR BOF COMPONENT DETAIL:

| S. No. | PARTICULARS | SPECIFICATIONS |
|-------------------|--------------------------|--|
| MECHANICAL | | |
| 1. | Sorter Motor | Bonfiglioli / equivalent |
| 2. | Sorter Motor Gearbox | Bonfiglioli / equivalent |
| ELECTRICAL | | |
| 1. | Variable Frequency Drive | Mitsubishi / equivalent |
| 2. | MCB | Schneider/ equivalent |
| 3. | OEN relay | OEN / equivalent |
| 4. | Vibrator Controller | Vibro Equipments / equivalent |
| 5. | Push button | Teknic / equivalent |
| 6. | Selector switch | Teknic / equivalent |
| 7. | Main ON/OFF switch | L & T Salzer |
| 8. | Terminals | Connectwell / equivalent |
| 9. | Cables | Polycab / Finolex / Spectra / equivalent |

7.7 LIMITING CONDITION FOR MACHINE PERFORMANCE:

➤ **Power Failure**

In the event of power failure, the process shall halt and shall start only on the restoration of power.

➤ **Control Panel Failure**

Failure in the control panel shall result in the stoppage of process. The process will start only on rectifying by operator intervention.

7.8 POWER AND UTILITY CONSUMPTION:

| S.No. | PARTICULARS | SPECIFICATIONS |
|--------------------------|-------------|-----------------|
| Power Consumption | | |
| 1. | Voltage | 415 V \pm 10% |
| 2. | Frequency | 50 Hz \pm 5% |



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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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12.0 ABBREVIATIONS:

| | | |
|-------|---|--------------------------------|
| PVT. | : | Private limited |
| LTD. | : | Limited |
| DQ. | : | Design Qualification |
| FCS | : | Filled Capsule Sorter |
| BOF. | : | Brought out of items |
| URS. | : | User Requirement Specification |
| MCB | : | Miniature Circuit Breaker |
| MOC | : | Material of Construction |
| % | : | Percentage |
| LPM | : | Liter per minutes |
| GMP | : | Good Manufacturing Practice |
| Hz | : | Hertz |
| H.P. | : | Horse Power |
| A.C. | : | Alternating Current |
| V | : | Voltage |
| mm | : | Millimeter |
| S.S. | : | Stainless Steel |
| GA | : | General Arrangement |
| M. S. | : | Mild Steel |
| NLT | : | Not Less then |
| NMT | : | Not More then |



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13.0 REVIEWED BY:

| DESIGNATION | NAME | SIGNATURE | DATE |
|-------------------------------|-------------|------------------|-------------|
| HEAD (ENGINEERING) | | | |

| DESIGNATION | NAME | SIGNATURE | DATE |
|------------------------------|-------------|------------------|-------------|
| HEAD (PRODUCTION) | | | |

| DESIGNATION | NAME | SIGNATURE | DATE |
|-------------------------------------|-------------|------------------|-------------|
| HEAD (QUALITY ASSURANCE) | | | |