



**INSTALLATION QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
CAPSULE POLISHING MACHINE &  
UNFILLED CAPSULE SEPARATOR**

**PROTOCOL No.:**

**INSTALLATION QUALIFICATION  
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FOR  
CAPSULE POLISHING MACHINE &  
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|                                |                        |
|--------------------------------|------------------------|
| <b>EQUIPMENT ID. No.</b>       |                        |
| <b>LOCATION</b>                | <b>Capsule Filling</b> |
| <b>DATE OF QUALIFICATION</b>   |                        |
| <b>SUPERSEDES PROTOCOL No.</b> | <b>NIL</b>             |



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**1.0 PRE – APPROVAL:**

**PREPARED BY:**

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

**REVIEWED BY:**

| DESIGNATION                             | NAME | SIGNATURE | DATE |
|---|------|-----------|------|
| OPERATING MANGER<br>(QUALITY ASSURANCE) |      |           |      |
| HEAD<br>(PRODUCTION)                    |      |           |      |
| HEAD<br>(ENGINEERING)                   |      |           |      |

**APPROVED BY:**

| DESIGNATION                 | NAME | SIGNATURE | DATE |
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| HEAD<br>(QUALITY ASSURANCE) |      |           |      |



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**2.0 OBJECTIVE:**

- To provide documented evidence for the Installation Qualification of Capsule Polishing Machine & Unfilled Capsule Separator.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

**3.0 SCOPE:**

- The scope of this installation qualification protocol cum report is limited to qualification Capsule Polishing Machine & Unfilled Capsule Separator (Make – Anchor mark) to be installed in the Capsule filling.
- This document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Capsule Polishing Machine & Unfilled Capsule Separator.

**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  |
|--------------------------|---|
| <b>Quality Assurance</b> | <ul style="list-style-type: none"><li>• Initiation, Authorization, Approval and Compilation of the Installation Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Qualification activity.</li><li>• Monitoring of Installation Qualification Activity.</li></ul>   |
| <b>Production</b>        | <ul style="list-style-type: none"><li>• Review Pre &amp; post Approval of Protocol cum Report.</li><li>• To Co-ordinate and support for Execution of Qualification study as per Protocol.</li></ul>   |
| <b>Engineering</b>       | <ul style="list-style-type: none"><li>• Review Pre &amp; post Approval of Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in Capsule Polishing machine &amp; unfilled capsule separator Installation Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li></ul> |



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**5.0 EQUIPMENT DETAILS:**

|                                 |  |
|---------------------------------|--|
| <b>Equipment Name</b>           | Capsule Polishing Machine & Unfilled Capsule Separator |
| <b>Equipment</b>                |  |
| <b>Manufacturer's Name</b>      |  |
| <b>Model</b>                    | DPM & UCS  |
| <b>Supplier's Name</b>          |  |
| <b>Location of Installation</b> | Capsule Filling  |

**6.0 BRIEF PROCESS DESCRIPTION:**

The entire equipment comprises of the following units:

**6.1 CAPSULE POLISHING UNIT**

- The capsule polishing machine consists of the polishing brush in the Teflon net assembly. The assembly is then enclosed inside the perforated SS cylindrical drum.
- The perforated drum is placed on the tray like structure for the collecting the powder generated during the polishing of the capsules.
- The powder from the tray is sucked by means of the vacuum blower into the de-dusting tank.
- The polishing assembly is placed at an inclined position & has the spring that directs the capsules to the outlet. During this process, the capsules get rubbed against the brush thereby polishing the capsules.
- The polishing assembly is driven by means of 0.5 HP electric motor through timing belt and pulley.
- A variable frequency drive is provided to vary the RPM of the polishing brush.
- The electrical control panel for the polishing unit such as MCB, VFD etc. is placed in the common SS control panel.

**6.2 UNFILLED CAPSULE SEPARATOR UNIT**

- The unfilled capsule separator unit consists of SS hopper assembly with outlet chutes at different heights.
- The unfilled capsule separator unit works on the principle of the air flow that has the varying effects on the unfilled capsules and properly filled capsules.
- The required airflow is developed by means of single phase blower and the airflow is directed in the circular fashion by means of a fixed impeller.



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- The capsules directed towards the periphery of the airflow by means of capsule guide pipe placed centrally on the impeller.
- The circular direction of the airflow imparts clockwise motion on the capsules. The filled or unfilled capsule will rotate at a higher orbit and the properly filled capsules will rotate at the lower orbit.
- The two outlet chutes are provided at different heights for collecting the capsule rotating at different orbits thus separating the unfilled capsules from the properly filled capsules.
- A dimmer is provided to vary the voltage of the blower thereby the airflow required for lifting the capsules. The airflow is adjusted depending on the filled weight of the capsules.
- The electrical control for the separator unit is provided in the common SS electrical control panel.

**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- Executed and approved design qualification document.
- Piping and instrumentation diagram (P& ID).
- Technical specification of equipment.
- Calibration certificate of components.
- Certificate of material of construction 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 IQ 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 GENERAL CHECKS AND LOCATION SUITABILITY:**

| Installation Checks                | Acceptance Criteria  | Observation |
|------------------------------------|--|-------------|
| Grouting And Mounting              | Should be grouted & mounted properly.  |             |
| Leveling                           | The equipment should be balanced and leveled properly.                             |             |
| Edges of parts                     | All the edges of metal parts should be grinded and no sharp edges should be there. |             |
| Welding of Joints                  | The welding joints should not have any burrs.                                      |             |
| Place of Installation              | Capsule filling  |             |
| Illumination in area               | NLT 300 Lux.   |             |
| Working space around the equipment | Should be sufficient for easy operation, cleaning, sanitation and maintenance.     |             |

**Checked By  
Sign & Date:**

**Verified By  
Sign & Date:**

**8.2 PRELIMINARY CHECK LIST – OVERALL CONDITION:**

| S.No. | Checks to be performed:  | Observation |
|-------|--|-------------|
| 1.    | Check for the overall dimensions   |             |
| 2.    | Check for the receipt of the consignment with reference to the packing list                |             |
| 3.    | Check for the horizontal leveling and proper positioning of the equipment                  |             |
| 4.    | Check for scratches on the machine body  |             |
| 5.    | Check for the condition of the electrical components in the control panel and their wiring |             |

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**8.3 COMPONENT LOCATION LIST:**

| S.No.             | Component  | Location   | Observation |
|-------------------|--|--|-------------|
| <b>Mechanical</b> |  |  |             |
| 1.                | Polishing motor  | Attached to the polishing assembly                   |             |
| 2.                | Timing pulley and belt   | Attached to the polishing assembly                   |             |
| 3.                | Polishing brush with Teflon net inside the SS perforated cylindrical housing | Assembled to the polishing assembly drive            |             |
| 4.                | Blower for Unfilled Capsule Separator Unit                                   | On the machine stand                                 |             |
| 5.                | Inlet & outlet chute   | Assembled to the UCS unit                            |             |
| 6.                | Capsule hopper with perforated plate and guide pipe                          | Assembled to the UCS unit                            |             |
| 7.                | Blower motor   | Assembled to the de-dusting blower inside SS trolley |             |
| <b>Electrical</b> |  |  |             |
| 8.                | MCB-Polishing Motor  | Inside Electrical Control Panel.                     |             |
| 9.                | MCB-Unfilled capsule separator blower  | Inside Electrical Control Panel.                     |             |
| 10.               | MCB for de-dusting blower motor  | Inside Electrical Control Panel.                     |             |
| 11.               | MCB for control circuit  | Inside Electrical Control Panel.                     |             |
| 12.               | Contactora for de-dusting blower motor                                       | Inside Electrical Control Panel.                     |             |
| 13.               | Overload relay for de-dusting blower motor                                   | Inside Electrical Control Panel.                     |             |
| 14.               | VFD for polishing motor  | Inside Electrical Control Panel.                     |             |
| 15.               | Dimmer for UCS blower  | Inside Electrical Control Panel.                     |             |
| 16.               | 8-pin OEN relay  | Control Panel.                                       |             |
| 17.               | Voltmeter for UCS blower   | On the operating panel                               |             |
| 18.               | Main ON / OFF Switch   | On the operating panel                               |             |
| 19.               | Selector switch for polishing motor  | On the operating panel                               |             |
| 20.               | Selector switch for UCS blower   | On the operating panel                               |             |
| 21.               | Selector switch for auto / manual operation                                  | On the operating panel                               |             |
| <b>Pneumatic</b>  |  |  |             |
| 22.               | Rotary connector   | Attached to the polishing brush assembly             |             |

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**8.4 DETAILED COMPONENT CHECK LIST – PHYSICAL SPECIFICATION:**

| S.No.             | Component Description  | Specification   | Observation |
|-------------------|--|---|-------------|
| <b>Mechanical</b> |  |   |             |
| 1.                | Unfilled Capsule Separator blower                              | Make – VBM Enterprises, 135 watts, 230 V, 2600 RPM, 0.5 A, 150 mm sweep |             |
| 2.                | Air Displacement Unit blower                                   | Make- Minivac, Model – SVRD 150, Vacuum -152 mm Hg, 235CFM              |             |
| 3.                | Timing belt for Polishing machine                              | Make- Mitsuboshi, 300H  |             |
| <b>Electrical</b> |  |   |             |
| 1.                | Polishing motor  | Make – Crompton<br>0.5 HP/0.37KW, 1400 RPM,<br>415V, 50 Hz              |             |
| 2.                | Air Displacement Unit blower motor                             | Make- Hindustan Motor, 2.2KW/3<br>HP, 2890 RPM, 415 V, 50 Hz            |             |
| 3.                | MCB for Polishing Motor  | Make – Schneider,<br>6A, 3poles   |             |
| 4.                | MCB for Air Displacement Unit blower                           | Make – Schneider,<br>16A, 3 poles                                       |             |
| 5.                | MCB for UCS blower & control circuit                           | Make – Schneider,<br>6A, 2poles   |             |
| 6.                | VFD for polishing motor  | Make – Mitsubishi,<br>Model –FR-D740-022-E16                            |             |
| 7.                | Contactora for Air Displacement Unit blower                    | Make – Siemens,<br>Model - 3TF30 10E                                    |             |
| 8.                | Overload relay for Air Displacement Unit blower                | Make – Siemens,<br>Model - 3UA50, 3.2-5 A                               |             |
| 9.                | 8-pin relay  | Make – Omron dc, 230 V coil<br>MY2N-GS                                  |             |
| 10.               | Dimmer   | Make – Mahesh Electric, 240 V I/P                                       |             |
| 11.               | Voltmeter  | Make – Mecos Model – SMP280   |             |
| 12.               | Main ON / OFF switch   | Make – Salzer, 16 A   |             |
| 13.               | Selector switch for polishing motor, UCS blower, auto / manual | Make – Teknic   |             |
| <b>Pneumatic</b>  |  |   |             |
| 1.                | Rotary pneumatic connector                                     | Make – SMC Pneumatics,<br>KSL-06  |             |
| 2.                | Tubing   | Make – SMC Pneumatics,<br>PU6 & PU8                                     |             |

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**8.5 VERIFICATION OF TEST CERTIFICATES:**

| S.No. | Component                          | Type of Certificate | Observation |
|-------|------------------------------------|---------------------|-------------|
| 1.    | Polishing motor                    | Test Certificate    |             |
| 2.    | UCS Blower                         | Test Certificate    |             |
| 3.    | Air Displacement Unit blower       | Test Certificate    |             |
| 4.    | Air Displacement Unit Blower motor | Test Certificate    |             |

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**8.6 POWER AND UTILITY CHECKLIST:**

| S.No. | Utility Parameter                          | Method of verification  | Acceptance Criteria                       | Observation |
|-------|--|-------------------------|---|-------------|
| 1.    | <b>Phase</b>                               | Visual Check            | 3 Phase                                   |             |
| 2.    | <b>Voltage Test<br/>(Using Multimeter)</b> | R ∅ N<br>Y ∅ N<br>B ∅ N | 415 V ± 10%<br>415 V ± 10%<br>415 V ± 10% |             |
| 3.    | <b>Frequency</b>                           | Multimeter              | 50 Hz ± 5%                                |             |

**Inference:**

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**Reviewed By  
 Sign & Date:**

**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.



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**10.0 DOCUMENTS TO BE ATTACHED:**

- Any other relevant documents.

**11.0 DEVIATION FROM PRE-DEFINED 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:**

|      |   |  |
|------|---|--|
| WHO  | : | World Health Organization                              |
| FDA  | : | Food and Drug Administration                           |
| CPS  | : | Capsule Polishing machine & Unfilled capsule Separator |
| cGMP | : | Current Good Manufacturing Practices                   |
| IQ   | : | Installation Qualification                             |
| SS   | : | Stainless Steel  |
| MOC  | : | Material of Construction                               |
| mm   | : | Millimeter   |
| AC   | : | Alternating Current                                    |
| HP   | : | Horse Power  |
| V    | : | Volt   |
| Hz   | : | Hertz  |
| NMT  | : | Not More Than  |
| RH   | : | Relative Humidity                                      |
| QA   | : | Quality Assurance                                      |
| IQ   | : | Installation Qualification                             |
| No.  | : | Number   |
| MOC  | : | Material of construction                               |
| NLT  | : | Not less than  |



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**17.0 POST APPROVAL:**

**INITIATED BY:**

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

**REVIEWED BY:**

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

**APPROVED BY:**

| DESIGNATION                 | NAME | SIGNATURE | DATE |
|-----------------------------|------|-----------|------|
| HEAD<br>(QUALITY ASSURANCE) |      |           |      |