INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

FILLED CAPSULE SORTER WITH MINI CAPSULE SORTER

EQUIPMENT ID. No.	
LOCATION	**Capsule Filling**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

CONTENTS

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR FILLED CAPSULE SORTER WITH MINI CAPSULE SORTER	PROTOCOL No.:

1.0 PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANGER (QUALITY ASSURANCE)			
HEAD (PRODUCTION)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Filled Capsule Sorter with Mini Capsule Sorter.
- 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 **Filled Capsule Sorter with Mini Capsule Sorter (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 Automatic Capsule Filling Machine.

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, Authorization, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Qualification activity. • Monitoring of Installation Qualification Activity.
Production	• Review Pre & post Approval of Protocol cum Report. • To Co-ordinate and support for Execution of Qualification study as per Protocol.
Engineering	• Review Pre & post Approval of Protocol cum Report. • Co-ordination, Execution and technical support in Filled Capsule Sorter with Mini Capsule Sorter Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution).

5.0 EQUIPMENT DETAILS:

Equipment Name	Filled Capsule Sorter With Mini Capsule Sorter
Equipment	
Manufacturer's Name	
Model	**MFCS**
Supplier's Name	
Location of Installation	Capsule filling

6.0 BRIEF PROCESS DESCRIPTION:

The entire equipment comprises of the following units:

6.1 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.

6.2 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.

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.

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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Sign & Date:

Verified By
Sign & Date:

8.3 COMPONENT LOCATION LIST:

S.No.	Component	Location	Observation
Mechanical			
1.	**Timing pulley and belt**	Fit with FCS drive assembly	
2.	**Filled capsule sorter motor**	Attached to the sorter assembly	
3.	**Filled capsule sorter gearbox**	Attached to the sorter assembly	
4.	**Sorter drum**	Assembled on the sorter shaft	
Electrical			
1.	**MCB for FCS Motor**	Inside the machine	
2.	**MCB for Vibrator Controller**	Inside the machine	
3.	**VFD for filled capsule sorter**	Inside the machine	
4.	**8-pin relay**	Inside the machine	
5.	**Main ON / OFF switch**	Operating panel	
6.	**Push button Start / Stop**	Operating panel	
7.	**Selector switch for FCS motor auto / manual**	Operating panel	
8.	**Push Button**	Operating panel	

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Sign & Date:

Verified By
Sign & Date:

8.4 DETAILED COMPONENT CHECK LIST – PHYSICAL SPECIFICATION:

S.No.	Component Description	Specification	Observation
Mechanical			
1.	**Filled Capsule sorter motor**	Make- Bonfiglioli 0.25HP//0.18kW, 1360 RPM	
2.	**Filled Capsule Sorter gearbox**	Make- Bonfiglioli Model – VF44F2100P63B5B3 Ratio- 100:1	
Electrical			
1.	**MCB for FCS Motor**	Make – Schneider, 6A, 3 poles	
2.	**MCB for Control Circuit**	Make – Schneider, 4 A, 2 pole	
3.	**VFD for filled capsule sorter**	Make- Mitsubishi, Model – FR-D740-022-E16	
4.	**Relay Card**	Make – Omron MY2N-GS	
5.	**Vibrator Controller**	Make- VBC 96	
6.	**Main ON / OFF switch**	Make – LT Salzer, 16 A	
7.	**Selector switch for FCS motor auto / manual**	Make – Teknic	
8.	**ON/OFF Push Button**	Make – Teknic	

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Sign & Date:

8.5 MATERIAL OF CONSTRUCTION:

S.No.	Components	Material of Construction (MOC)	Observation
1.	**Capsule guide plate**	MOC Certificate	
2.	**S.S. Plate**	MOC Certificate	
3.	**Tray**	MOC Certificate	
4.	**Rejection Tray**	MOC Certificate	
5.	**Rotor cover**	MOC Certificate	

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Verified By
Sign & Date:

8.6 VERIFICATION OF TEST CERTIFICATES:

S.No.	Component	Type of Certificate	Observation
1.	**Main motor**	Test Certificate	
2.	**Main motor gearbox**	Test Certificate	
3.	**Powder motor**	Test Certificate	
4.	**Powder motor gearbox**	Test Certificate	
5.	**Vacuum pump**	Test Certificate	
6.	**Vacuum pump motor**	Test Certificate	
7.	**Blower**	Test Certificate	
8.	**Blower motor**	Test Certificate	
9.	**Powder sensor**	Test Certificate	
10.	**Capsule sensors**	Test Certificate	
11.	**pellet sensor**	Test Certificate	
12.	**Tablet Sensors**	Test Certificate	
13.	**Main Air Pressure switch**	Test Certificate	

Checked By
Sign & Date:

Verified By
Sign & Date:

8.7 POWER AND UTILITY CHECKLIST:

S.No.	Utility Parameter	Method of verification	Acceptance Criteria	Observation
1.	**Phase**	Visual Check	3 Phase	
2.	**Voltage**			
3.	**Test** **(Using Multi meter)**	R ⏚ N Y ⏚ N B ⏚ N	415 V ± 10% 415 V ± 10% 415 V ± 10%	
4.	**Frequency**	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.

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
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
OD	:	Oral Solid Dosage
FCS	:	Filled Capsule Sorter
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

17.0 POST APPROVAL:

INITIATED 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)			