PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR TABLET / CAPSULE SORTER	PROTOCOL No.:

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1.0 PROTOCOL APPROVAL:

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved. The protocol cannot be used for execution unless approved by the following signatories.

This Installation Qualification protocol of Capsule/Tablet Sorter has been reviewed and approved by the following signatories:

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		

2.0 OVERVIEW:

2.1 OBJECTIVE:

The objective of developing and executing this protocol is to collect sufficient data pertaining to the Capsule/Tablet Sorter and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the Capsule/Tablet Sorter was installed as required in Inspection.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Capsule/Tablet Sorter received matches the design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

The installation qualification protocol shall be followed for installation qualification of Capsule/Tablet Sorter in Inspection of Production Cepha Oral manufacturing facility.

This protocol defines the methods and documentation that shall be used to evaluate the system installation in accordance with the specifications and intended use. Successful implementation of this protocol shall verify that the equipment installed is as per the requirements specified.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are as follows:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.

- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The installation checks, operational checks, calibration, SOP identification, identification features, identification of utility supply shall be carried out by engineering persons.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production and Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.

2.5 EXECUTION TEAM:

The satisfactory installation of the Capsule/Tablet Sorter shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Capsule/Tablet Sorter is installed satisfactorily.

Execution team is responsible for execution of installation qualification of Capsule/Tablet Sorter. Execution team comprises of:

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The Capsule/Tablet Sorter shall meet the system description given in design specification.

3.2 The Capsule/Tablet Sorter shall meet with the acceptance criteria mentioned under the topic, "Identification of major components".

3.3 All material of constructions of the contact parts to be checked as per the specifications.

4.0 REQUALIFICATION CRITERIA:

The machine has to be requalified if:

- There are any major changes, which affect the performance of the equipment.
- After major breakdown, maintenance is carried out.
- As per requalification date and schedule.

5.0 INSTALLATION QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	Capsule/Tablet Sorter
Supplier / Manufacturer	:	ACG Pam pharma Technologies Pvt. Ltd.
Model	:	CTS - 100
Serial No.	:	.....
Dimension In MM	:	1695 (L) x 620 (W) x 1485 (H)
Location	:	Inspection

Capsule/Tablet Sorter comprises of following components:

1. Main Body
2. Hopper with Vibratory Pan
3. Roller conveyor Assembly
4. Roller Rotating Assembly
5. Control panel
6. Mirror Assembly
7. Tube light Assembly

1. Main Body:

The main body consists of a stainless steel structure. On the structure are mounted aluminium plates, which house the drives for the roller conveyor assembly and roller rotating assembly. The sides are enclosed by stainless steel cover.

2. Hopper with Vibratory pan:

It consists of a SS 316 hopper with polycarbonate front cover. It has a gate which enables to regulate the flow of the product on to a vibratory pan. The pan is a tray with perforations which transfers the products on the rollers. The powder adhering to the product falls off through the perforated holes into a container below it.

3. Roller conveyor Assembly:

This is through a chain and sprocket drive. The chain is guided through Teflon guides.

4. Roller Rotating Assembly:

The drive for rotating motors is through a motor which drives pulleys holding silicone ropes.

5. Control panel:

This is mounted below the structure and includes the variable frequency drive, contactor, relay MCB (Miniature Circuit Breaker) & SMPS (single mode power supply). The vibrator controller is mounted on the outside cover of the panel.

6. Mirror Assembly:

The mirror is mounted on a bracket on the rear side.

7. Tube light Assembly:

This includes a tube light of 8 W & mounted on the rear side of the machine. A toggle switch is provided on the tube light.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST:

5.2.1 In case of identification of major component actual observation should be written in specified location.

5.2.2 In case of the compliance of the test actual observation should be written in specified location.

5.2.3 For identification of utilities actual observation should be written in specified location.

5.2.4 Give the detailed information in the summary and conclusion part of the installation Qualification report.

5.2.5 Actual observation of the component should be written in specified location.

5.2.6 Whichever column is blank or not used ‘NA’ shall be used.

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5.3 INSTALLATION CHECKLIST:

Installation checklist is as follows:

S.No.	Statement	Method of Verification	Actual observation	Checked By Sign/Date
1.	Verify the purchase order copy and PO no. shall be written in observation column.	Physically		
2.	Verify that the "As Built" drawing is complete and represents the design concept.	Physically		
3.	Verify that major components are securely anchored and shock proof.	Physically		
4.	Verify that there is sufficient room provided for servicing.	Physically		
5.	Verify that all piping and electrical connections are done according to the drawings.	Physically		
6.	All access ports are examined and cleared of any debris.	Physically		
7.	Safe electrical connections.	Physically		
8.	Sufficient room provided for maintenance.	Physically		
9.	Equipment identification nameplate visible.	Physically		
10.	Units installed on foundation are secure in place as per manufacturer's recommendations.	Physically		
11.	Verify that there is no observable physical damage.	Physically		

Remark: ----------

Reviewed by (Sign/Date)

5.4 IDENTIFICATION OF MAJOR COMPONENTS:

Check all the critical components and fill the inspection checklist.

System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
Hopper with Vibratory Tray	Position	Fitted on the base of vibrator coil	Physically		
	Material of construction	SS 316	Test certificate/ Molybdenum Kit		
	Surface Finish	320 grit Mirror finish	Technical Specification/ Test certificate		
Main Drive Motor	Position	On the top structure	Physically		
	Make	Bonfiglioli	Physically		
	Spec.	BN63B4, 0.18 Kw, 1320 RPM, 1.23 Amps.	Physically		
	Protection Class	IP 55	Physically		
Gear box for Main Drive Motor	Position	Fitted to main drive motor	Physically		
	Make	Bonfiglioli	Physically		
	Model	VF44U60P63B5B3	Physically		
Roller Drive Motor	Position	On the top structure	Physically		
	Make	SPG Co., Ltd.	Physically		
	Model	S8I25GX-V12CE (Speed Motor) S8KA30B1(Gear Head)	Physically		
	Spec.	0.025 Kw, 0.25 Amp, 1400 RPM	Physically		
Chain	Position	Drive assembly, Cam switch box	Physically		
	Make	Diamond	Technical Specification/ Test certificate		
	Spec.	½" pitch x 5/16" roller dia. 33 link	Physically/ Test Certificate		
Timer Belt	Position	Drive assembly	Physically		
	Make	Optibelt	Physically		

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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	Spec.	ZR300L, 80 Teeth 19 mm width, 9.525 pitch 762 mm LG	Physically/ Technical Specification/ Test certificate		
Vibrator Controller	Position	Fitted on the outside of electrical control panel	Physically		
	Make	Electroquip	Physically		
	Model	VBC-96	Physically		
Speed Control Unit	Position	Fitted on the front side of electrical control panel	Physically		
	Make	SPG Co., Ltd.	Physically		
	Model	SUA251X-V12	Physically		
	Spec.	25 W, 220V/50 Hz, 0.25 Amp.	Physically		
Tube Light	Position	Fitted to rear side of machine	Physically		
	Make	Niti	Physically/ Technical Specification		
	Spec.	8 W, 230 V	Physically		
A.C. Drives	Position	Control panel assembly	Physically		
	Make	Schneider Electric	Physically		
	Spec.	ATV12H037M2, 0.37 Kw/ 0.5 Hp	Physically		
Foot Pedal Switch	Position	On bracket (Foot rest)	Physically		
	Make	Brisk Industries	Physically		
	Spec.	Model No- BFS-13, 10 Amp, 250 VAC	Physically		
Vacuum Pickup Gun	Position	On nozzle bracket	Physically		
	Make	Festo	Physically		
	Spec.	Model- LSP-¼-D 35528	Physically		
	Operating pressure	6 bar (6 Kg/ cm^2)	Physically		
	Maximum pressure	10 bar	Physically		
Vacuum up Pick Motor	Position	Above blower casing	Physically		
	Make	Hindustan Electric Motors	Physically		

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System Components	Design Specification		Method of Verification	Actual Observation	Checked By Sign/Date
	Type	1.5 Kw, 2.0 Hp, 2860 RPM, 3.10 Amp, 3 Ph	Physically		
	Protection	IP 55	Physically		
Operating panel	Main switch ON/OFF	To start and stop the machine	Physically		
	Power ON indicator.	To indicate start and stop of machine.	Physically		
	Main Manual/Auto selector switch	To select machine in Manual/Auto mode.	Physically		
	Main motor Manual/Auto selector switch	To run motor in Manual/Auto mode.	Physically		
Operating panel	Vibrator (COARSE and FINE) controller	To increase/ decrease the vibration	Physically		
	Tube light ON/OFF selector switch.	To ON / OFF the tube light	Physically		
	Conveyor speed regulator(Speed Potentiometer)	To control the speed of conveyor	Physically		
	Roller speed regulator	To control the speed of roller	Physically		
	Emergency stop	Switch off the machine in case of emergency	Physically		
	Foot operated switch	To stop and start the conveyor belt	Physically		

Remark: ----------

Reviewed by (Sign/Date)

5.5 VERIFICATION OF MATERIAL OF CONSTRUCTION:

Material of construction should be verified by test certificates of respective material, apart from that SS material should be verified by molybdenum kit / test certificate.

Name of Components	Material of Construction	Method of Verification	Observation	Checked By Sign/Date
Product Hopper	SS 316	Molybdenum Kit/Test certificate		
Rejected Product Collection Box	SS316	Molybdenum Kit/Test certificate		
Vibrator tray	SS316	Molybdenum Kit/Test certificate		
Exit Chute	SS316	Molybdenum Kit/Test certificate		
Roller	Rubber (Food Grade)	Test certificate		
Cladding Sheet	SS304	Molybdenum Kit/Test certificate		

Remark: ----------

Reviewed by (Sign/Date)

5.6 IDENTIFICATION OF SUPPORTING UTILITIES:

Utility	Method of verification	Observation	Checked by Sign/ Date
1. Electricity: 1 phase, 220V AC, 50Hz supply with neutral and proper earthing.	Physically and with clamp meter		
2. Vacuum Pick Unit: Power- 415 V, 50 Hz.	Physically and with clamp meter		

Remark: ----------

Reviewed by (Sign/Date)

5.7 IDENTIFICATION OF SAFETY FEATURES: Identify and record the safety features (if any) and their function in following tables:

Safety Features Description	Function	Method of Verification	Observation	Checked By Sign/ Date
Earthing	To avoid electrical shocks due to leakage current.	Physically		
Emergency stop button	To stop machine immediately in case of emergency	Physically		

Remark: ----------

Reviewed by (Sign/Date)

5.8 IDENTIFICATION OF COMPONENT TO BE CALIBRATED:

Name of Components	Range	Make	Location	Identified By Sign/Date

Remark: ----------

Reviewed by (Sign/Date)

5.9 IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of Capsule/ Tablet inspection machine:

S.No.	SOP TITLE	IDENTIFIED BY	DATE

Remark: ----------

Reviewed by (Sign/Date)

5.10 VERIFICATION OF DRAWING AND DOCUMENTS:

Following documents are reviewed and attached as listed below:

S.No.	DRAWING AND DOCUMENT DETAIL	CHECKED BY (SIGN)	DATE

Remark: ----------

Reviewed by (Sign/Date)

5.11 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any): ----------

Done By & Date: **Verified By & Date:**

5.12 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):

Following deficiency was verified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

Deviation accepted by
(Sign/Date)

Deviation Approved by
(Sign/Date)

6.0 INSTALLATION QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

Prepared By
Sign/Date

Checked By
Sign/Date

6.3 FINAL REPORT APPROVAL:

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies (if applicable) are documented, approved and attached to this protocol. Signatures in the block below indicate that all items in this qualification report of Capsule/Tablet Sorter have been reviewed, found to be acceptable and all variations or discrepancies (if applicable) have been satisfactorily resolved. After the successful installation qualification of the Capsule/Tablet Sorter, the equipment can be taken for Operational qualification.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		