 **PHARMA DEVILS**	**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CAPSULE/TABLET 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 authorities.

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

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

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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. Define the qualification requirements and acceptance criteria for the machine, to prove that each operation proceeds as per design specification and the tolerances prescribed in the document, are same at utmost transparency.

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 Scope of this protocol is limited to the operational Qualification of Capsule/Tablet Sorter in Inspection.

Once the operational qualification of Capsule/Tablet Sorter has been completed successfully, the equipment shall be preceded for the performance qualification.

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 operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.
- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production/ 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 operation 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 operational and is satisfactorily working.

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

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE

3.0 ACCEPTANCE CRITERIA:

3.1 The equipment shall be operational as per its specified operating instructions.

3.2 All SOP's for the equipment to be verified and checked.

3.3 Training is imparted to all the concerned personnel.

3.4 All the functionality of equipment components to be checked.

3.5 RPM of motor should be in the range of ±5% deviation.

4.0 REQUALIFICATION CRITERIA:

The machine shall be requalified if:

- There are any major changes, which affect the performance of equipment.
- During preventive maintenance or break down maintenance, if any major components are replaced and this affect the performance of equipment.
- As per requalification date and schedule.

5.0 OPERATIONAL 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(mm)	:	1695 (L) x 620 (H) x 1485 (W)
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

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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 & Smps. 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 the compliance of the test actual observation should be written in specified location.

5.2.2 For identification of the components of the equipment and utilities actual observation should be written in specified location.

5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.

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

5.3 TEST INSTRUMENT DETAILS:

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration due date	Certificate Number

Checked by Date:

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

Reviewed by (Sign/Date)

5.4 Verification of Calibrated component:

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard, which is to be used for the verification of the operation of Capsule/ Tablet Sorter.

S. No.	Name of Instrument	Location	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate number

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

Reviewed by (Sign/Date)

5.5 VERIFICATION OF FUNCTIONAL CHECKS:

Describe each critical component and check them and fill the inspection checklist

5.5.1 Verification of functionality major component:

Name of System Component	Specified Function	Method of Verification	Observation	Verified By Sign/Date
Main selector ON/OFF switch	Supply of power is controlled by ON/OFF selector switch.	Physically by challenging		
Hopper	It consists of SS hopper with polycarbonate front cover. It has a gate which enables to regulate the flow of the product on to a vibratory pan.	Physically by challenging		
Vibrating Pan	Transfer the products on the rollers.	Switch on the vibrating pan selector switch and check physically by challenging.		
Vibrating Pan	Vibrator position can be adjustable to different positions (zero, full, half).	Physically by challenging.		
Roller conveyer assembly.	This is through a chain and sprocket drive. The chain is guided through Teflon guides. Direction of rotation of roller conveyer assembly should be clockwise.	Switch on the roller conveyer assembly and check physically by challenging.		
Roller rotating assembly.	The drive for Rotating motor is through a motor which drive pulley holding silicone ropes.	Switch on the roller rotating assembly and check physically by challenging.		
Mirror Assembly	The mirror is mounted on a bracket on the rear side. Such that objects on belt should be visible.	Physically by challenging.		

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Name of System Component	Specified Function	Method of Verification	Observation	Verified By Sign/Date
Castor Wheel	For movement of machine. The castors are provided with a locking arrangement.	Physically by challenging		
Light and light intensity.	Switch on/off the light and check visually. Light intensity checked at different condition Limit: NLT 300 lux. 1) Area light is "ON" and inspection light "ON". 2) Area light "OFF" and inspection light is "ON".	Physically by challenging		
Roller conveyer assembly speed	Increase/decrease speed can be possible by speed regulating knob.	Physically by challenging.		

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

Reviewed by (Sign/Date)

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5.5.2 Verification of operational key functionality:

Name of System Component	Specified Function	Method of Verification	Observation	Verified By Sign/Date
Main Manual/Auto selector switch	To select machine in Manual/Auto mode.	Physically by challenging.		
Main motor Manual/Auto selector switch	To run motor in Manual/Auto mode.	Physically by challenging.		
Tube light ON/OFF selector switch	To switch on/off tube light.	Physically by challenging.		
Conveyor speed regulator (Speed Potentiometer).	To control speed of conveyor.	Physically by challenging.		
Roller speed regulator.	To control speed of roller.	Physically by challenging.		
Emergency stop.	Switch off the machine in case of emergency.	Physically by challenging.		
Foot operated switch.	To stop and start the conveyor belt.	Physically by challenging.		

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

Reviewed by (Sign/Date)

5.6 VERIFICATION OF SUPPORTING UTILITIES:

Utility	Method of Verification	Observation	Verified By Sign/Date
Electricity: 1 phase, 220V AC, 50Hz supply with neutral and proper earthing.	By clamp meter.		

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

Reviewed by (Sign/Date)

5.7 VERIFICATION OF SAFETY FEATURE:

Identify and record the safety features (if any) and their function in following tables:

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

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

Reviewed by (Sign/Date)

5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of Capsule/ Tablet Sorter.

S.No.	SOP Title	SOP Number	Verified By (Sign/Date)

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

Reviewed by (Sign/Date)

5.9 TRAINING RECORD OF PERSONNEL (S):

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

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

Reviewed by (Sign/Date)

5.10 LIST OF ANNEXURES:

Annexure No.	Document Title

Remarks (if any)**:**

_____

_____

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

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

Following deficiency was identified 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 OPERATIONAL 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 indicates that all items in this Operational qualification report of Capsule/Tablet Sorter has been reviewed, found to be acceptable and all variations or discrepancies(if applicable) have been satisfactorily resolved.

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