PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC CAPSULE FILLING MACHINE

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC CAPSULE FILLING MACHINE	PROTOCOL No.:

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PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR AUTOMATIC CAPSULE FILLING MACHINE	PROTOCOL No.:

1.0 PROTOCOL 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 that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for Automatic Capsule Filling Machine **(**Make – anchor mark**)** to be installed in the Capsule filling.
- This Protocol will define the methods and documentation used to qualify the Automatic Capsule Filling Machine for PQ.

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:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Initiation, Approval and Compilation of the Performance Qualification. • Co-ordination with Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Automatic Capsule Filling Machine.
Equipment	
Manufacturer's Name	
Model	PHARMAFILL A120
Supplier's Name	
Location of Installation	Capsule filling

6.0 SYSTEM DESCRIPTION:

The entire equipment can be classified into two zones production zone and non-production zone:

6.1 Production Zone

- The production zone encompasses the upper portion of the Capsule Filling Machine and is enclosed by the acrylic doors followed by interlock system.
- The production zone includes the loader assembly, powder assembly with rejection system, un-separated capsule rejection assembly, locking assembly, ejection assembly and turret assembly.
- The loader assembly consists of the loader body with magazine & finger block assembly, raceway and pusher block. The capsules descend from magazine onto the slots of the raceway and the pusher block then orients the capsules on the raceway. The finger block then releases the capsule with cap up and body down position.
- The powder assembly consists of the tamping punches, punch guide plate, scrapper plate, dosing disc with drum. The dosing disc is indexed with six station indexers. The tamping pins are used to tamp the powders at the 5 stations and at the 6th station the slug is ejected out into the body of the capsule placed in the bottom segment.
- The rejection assembly consists of the rejection bracket that reciprocates on every stroke of the machine. The rejection bracket aids in raising the un-separated capsule. The capsules are then sucked by means of the vacuum blower.
- Locking assembly consists of locking pins that reciprocate on every stroke of machine. The pins are used to lock the filled capsules against fixed plate on the opposite side.
- The ejection assembly consists of the ejection pins that reciprocates on every stroke of the machine and ejects the filled capsule into the outlet chute with blow of pneumatic air.
- The turret assembly consists of turret, top cam, bottom cam, top segment and bottom segment. The turret is driven by the twelve-station indexer.

The following operations are performed at each station

- Station for loading and separation of the capsules (ROW 1)
- Station for loading and separation of the capsules (ROW 2)
- Upward movement of the top segment and backward movement of the bottom segment
- Station for filling Pellet / Tablet into the capsule
- Station for filling powder into the capsule
- Station for filling Pellet / Tablet into the capsule
- Station for rejecting the un-separated capsules
- Downward movement of the top segment and forward movement of the bottom segment
- Station for locking the capsule
- Station for idle station
- Station for ejecting the capsule
- Station for cleaning the segments

6.2 Non-Production Zone

- The non-production zone encompasses the lower portion of the machine and is enclosed within the SS panel sheets. It also includes the area above the production zone of the machine
- The non-production zone includes the entire drive assembly. The drive assembly consists of the brake motor & gearbox assembly connected to the main shaft via chain & sprocket assembly.
- The cams for the respective stations are mounted on the main shaft and the drive to the station is through cam follower, lever and tie rod attached to the assembly in the production zone.
- The 12-station indexer for turret and 6 station indexers for powder filling assembly is located in the non-production zone at the bottom side of the top plate. The drive to the indexer from the main shaft is through separate chain & sprocket arrangement.
- The electrical control panel is placed separately in the Capsule filling room beside the main machine. It includes the MCB, contactors, O/L relay, PLC, relay card, VFD, SMPS terminals etc
- The drive to the powder hopper assembly to stirrer is from the separate motor & gearbox assembly. The motor & gearbox assembly is placed in the area below the production zone.

6.3 Pellet / Granule filling attachment (2 Nos.)

The Pellet feeding assembly consists of the Pellet hopper, dosage adjustment block, dosage adjustment finger plate and lower fixed block. The Pellets are transferred from Pellet hopper into the dosage adjustment block through Pellet hopper discharge pipe. The sliding plate is reciprocated by means of the cam lever mechanism which delivers the Pellets into the capsule body. Amount of dosage can be varied with the dosage adjustment finger plate.

Machine will be supplied with 1 No. of pellet filling attachment each for capsule size #0 & capsule size #3

6.4 Tablet filling attachment (2 Nos.)

The tablet feeding assembly consists of the vibratory bowl, magazine, sliding plate and lower fixed block. The tablets are oriented and transferred into the magazine from the vibratory bowl. The tablets are then transferred into the lower fixed block through the reciprocating action of the sliding plate. The sliding plate is reciprocated by means of the pneumatic cylinder arrangement. Tablet filling attachments for capsule size #0 will be fits either side of the powder filling station.

Machine is provided with the special feature of rejecting the single capsule for No Tablet filling & if the 5 capsules are observed continuously without tablet machine will stop. These will give exact the quantity of capsule rejected due to NO Tablet Filling.

6.5 Control System

The Control system for the equipment is a standard control based system. Control panel with all related electrical and pneumatic components is provided separately from main machine. The Operating panel cum control panel provided is of SS 304 in construction.

7.0 REASON FOR QUALIFICATION:

New equipment in Capsule filling.

8.0 SITE OF STUDY:

Capsule filling

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two year±1month.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

10.1 VERIFICATION OF DOCUMENTS:

Training of Qualification Team:

- All the persons involved in the execution of Requalification Protocol must be trained in all aspects of the qualification activity including the test methodology, acceptance criteria and safety precautions to be followed during working at floor.

10.2 CALIBRATION STATUS OF TEST INSTRUMENTS:

- Verify the Calibration Status of Instruments used in Performance Qualification.

11.0 TESTS AND CHECKS:

11.1 VERIFICATION OF DOCUMENTS:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Capsule Filling machine.
- SOP for Preventive Maintenance of Capsule Filling machine.

.**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.
- Supporting documents would form a part of the PQ report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

11.2 EVALUATION OF PERFORMANCE USING DRUG PRODUCT:

- **Objective:**

  To evaluate and to provide documented evidences for performance of equipment for proper filling of Hard Gel capsules. The objective of the test is to determine whether the machine is able to properly fill the capsules.

- **Test & Checks:**
  - Physical parameter observation.
  - Speed qualification at full hopper.
  - Speed qualification at low hopper.

- **Method:**
  1. The test should be carried out for three batches.
  2. Switch "ON" the machine & operate as per SOP.
  3. Physical parameter like description, capsule size, weight of empty capsule, uniformity of fill weight, avg. weight of filled capsule, locking length and disintegration time has been verified and recorded.
  4. Speed qualification (Minimum and maximum) at full hopper has been performed, during activity In process checks like physical appearance, de- dusting and polishing, capsule denting, pin hole, telescoping and double cap, uniformity of weight should be verified and same recorded in reports.
  5. Speed qualification (Minimum and maximum) at low hopper has been performed, during activity In process checks like physical appearance, de- dusting and polishing, capsule denting, pin hole, telescoping and double cap, uniformity of weight should be verified and same recorded in reports.

- **Acceptance Criteria:**
  - Observation of samples of filled capsules should be within the limit specified for products.
  - Avg. Wt. of Filled Capsules, Uniformity of Wt. of Filled Capsules, Avg. Fill Weight, Uniformity of Fill Weight of all individual 20 capsules observed should be within limit.
  - Physical appearance, De- dusting and polishing, Capsule denting, Pin hole, and Disintegration Time in Capsule observed.

11.3 TABLET COUNTER CHALLENGE TEST:

- **Objective:**

  To evaluate and to provide documented evidences for performance of equipment for proper working of tablets attachment sensor. The objective of the test is to determine whether the tablets attachment sensor is able to detect missing tablets.

- **Missing Tablet from attachment-1:**

  Procedure:

  Hold the tablet feeding from attachment-1.Record the observation for same. This procedure repeated for low, optimum & high speed.

  Acceptance criteria:

  Machine should stop and notification shows on HMI and capsules should be rejected in rejection box for missing tablets.

- **Missing Tablet from attachment-2:**

  Procedure:

  Hold the tablet feeding from attachment-2.Record the observation for same. This procedure repeated for low, optimum & high speed.

  Acceptance criteria:

  Machine should stop and notification shows on HMI and capsules should be rejected in rejection box for missing tablets.

- **Missing Tablet from attachment-3:**

  Procedure:

  Hold the tablet feeding from attachment-3.Record the observation for same. This procedure repeated for low, optimum & high speed.

  Acceptance criteria:

  Machine should stop and notification shows on HMI and capsules should be rejected in rejection box for missing tablets.

- **No Tablets in capsule:**

  Procedure:

  Hold the tablet feeding from attachment-1, 2 & 3.Record the observation for same. This procedure repeated for low, optimum & high speed.

  Acceptance criteria:

  Machine stop after 5 continuous empty capsule and Machine should stop and notification shows on HMI for no tablets in capsule.

11.4 EMPTY CAPSULE SORTER CHALLENGE TEST:

- **Objective:**

  To evaluate and to provide documented evidences for performance of equipment for proper working of empty capsule sorter. The objective of the test is to determine whether the tablets attachment sensor is able to detect empty capsule.

- **Procedure:**

  Take 95 filled and 5 empty capsules for test, Pass through ECS at Different voltage range.

- **Acceptance criteria:**

  All 5 empty should be capsule rejected.

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

- Verification of documents.
- Verification of performance using Drug product.
- Tablet counter challenge test.
- Empty capsule sorter challenge test.

13.0 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.

14.0 DOCUMENTS TO BE ATTACHED:

- All relevant documents.

15.0 NON COMPLIANCE:

- In case of any non compliance observed during PQ, inform to Head QA for necessary action.
- The Head QA shall study the impact of non compliance. If non compliance is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

16.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

18.0 ABBREVIATIONS:

PVT.	:	Private limited
LTD.	:	Limited
IQ.	:	Installation Qualification
MCB	:	Miniature Circuit Breaker
VFD	:	Variable Frequency Drive
SMPS	:	Switched mode power Supply
PLC	:	Programmable logical control
cGMP	:	Current Good Manufacturing Practices
QA	:	Quality Assurance
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
BMR	:	Batch manufacturing Record
mg	:	Milligram
Kg	:	kilogram
Avg.	:	Average
NLT	:	Not Less Than
Wt.	:	Weight
ECS	:	Empty capsule sorter
WHO	:	world health organization
HMI	:	Human machine inference