PERFORMANCE QUALIFICATION

PROTOCOL

FOR

CAPSULE HAND FILLING MACHINE

EQUIPMENT ID No.	
LOCATION	**Hard Gelatin Capsule Section**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	

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

PROTOCOL CONTENTS

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

1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing as per the parameter defined in operational qualification and that it gives result as per the predetermined acceptance criteria.
- To demonstrate that the system will operate reproducibly and consistently within its operating range.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.
- The document also provides the observed and obtained values indicating compliance to the PQ Protocol.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the **Capsule Hand Filling Machine (Make- Pam Pharmaceutical and Allied Machinery Pvt. Ltd.)** installed in the Hard Gelatin Section.
- Capsule Hand Filling Machine previously installed in Hard Gelatin Capsule Section, Now Equipment Transfer to other Hard Gelatin Capsule Section.
- This Protocol will define the methods and documentation used to qualify the Capsule Hand 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 cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Authorization, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Performance Qualification Protocol.
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	Capsule Filling machine
Equipment	
Manufacturer's Name	Pam Pharmaceutical and Allied Machinery Pvt. Ltd.
Model	MF 30
Supplier's Name	Pam Pharmaceutical and Allied Machinery Pvt. Ltd.
Location of Installation	Hard Gelatin Capsule Section

6.0 SYSTEM DESCRIPTION:

Capsule Hand Filling Machine is compact and versatile model for filling various powders, granules, tablets into hard gelatin capsules and is very useful to other medicine manufactures, cosmetic, food, veterinary, biotech and allied industry.

300 Holes Capsule Hand Filling Machine is a compact model suitable for R & D purpose, lab purpose and trial purpose before full production. Capsule Hand Filling Machine is simple to operate, can be handled by unskilled labor, easy to dismantle, save time and make the whole process hygienic and very easy.

Main body made of mild steel material with hard chrome plating and all contact parts made of stainless steel 304/ 316. Handle locking arrangement makes the operator to lift the loading plate without fear of damaging the capsules. Pressing is achieved by cam system which also saves time to press the plunger as compared to screw system. High rate of production with minimum rejection and variation can easily fill powders, pellets in all sizes of hard gelatin capsules.

The machine is manufactured to suit the following capsule size combination 00/0/1/2/3/4 and 5.

7.0 REASON FOR QUALIFICATION:

- Change of Location.

8.0 SITE OF STUDY:

Hard Gelatin capsule Section.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two years time period.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE – QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Preparation of SOP for Operation & Cleaning of Capsule Hand Filling Machine.
- Preparation of SOP for Preventive Maintenance of Capsule Hand Filling Machine.

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 Hand Filling Machine.
- SOP for Preventive Maintenance of Capsule Hand 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:

11.2.1 Objective:

To evaluate and to provide documented evidence for the 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.

11.2.2 Test & Checks:

- Capsule Size
- Weight of Empty Capsule
- Uniformity of Fill Weight
- Avg. Weight of Filled Capsule
- Locking length
- Disintegration Time
- Capsule denting
- Pin hole

11.2.3 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 of Capsule should be within the limit specified for products.

12.0 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.

13.0 DOCUMENTS TO BE ATTACHED:

- Operation and Maintenance Manual.
- Any other Relevant Documents.

14.0 NON COMPLIANCE:

- 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 shall 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.

15.0 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.

16.0 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.

17.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

- Concerned department Review the Documents after Execution.

18.0 CONCLUSION

- Clearly stating the achievement or non-compliance of the acceptance criteria, effect of the deviations made during the Qualification and in case of failure, investigation carried out and their findings.

19.0 RECOMMENDATION

- Recommendation shall be made on the basis of review made according to conclusion derived by representative of each concerned department.

20.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
DQ	:	Design Qualification
ID.	:	Identification
IQ	:	Installation Qualification
Ltd.	:	Limited
MOC	:	Material of Construction
OQ	:	Operational Qualification
PQ	:	Performance Qualification
Pvt.	:	Private
SOP	:	Standard Operating Procedure
SS	:	Stainless Steel
WHO	:	World Health Organization