PERFORMANCE QUALIFICATION

PROTOCOL

FOR

STRIP PACKING MACHINE

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

PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR STRIP PACKING MACHINE	PROTOCOL No.:

PROTOCOL CONTENTS

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR STRIP PACKING MACHINE	PROTOCOL No.:

1.0 PROTOCOL 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 consistently, repeatedly and reproducibly within its established operating range and the results of all the 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 the **Strip Packing Machine** installed.
- This Protocol will define the methods and documentation used to qualify the Strip Packing 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	• 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 Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of 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	Strip Packing Machine
Equipment	…….
Manufacturer's Name	Satellite engineers
Model	GMP Model
Supplier's Name	Satellite engineers
Location of Installation	Packing line

6.0 SYSTEM DESCRIPTION:

Feeding System:

Product is fed into the hopper from where it is guided into the Bowl mounted on a Vibrator. The product on the Bowl is evenly distributed and guided through the tracks on the Bowl into the Chute Channel and the feed rate of the Product from the Bowl to the Chute Channel is controlled by the Vibrator. The Product from the Chute is released onto the Sealing Roller by the Cam Operated Release Pin.

Sealing System:

The set of Sealing Rollers draws the heat sealing Packing Material (Foils) from 2 sets of front adjustable type of friction brake system Foil Holder Assembly and Foil running tubes. The sealing Rollers are heated to the required temperature by the Cartridge Heaters inserted into the individual Rollers. Adequate pressure is applied onto the Sealing Rollers so that both the foils get sealed at the time of contact while passing through the sealing roller. At this stage the product which is released onto the cavity of the rollers gets packed and sealed in the foils. Batch Coding Unit: The left hand Foil before being drawn by the Sealing Rollers passes through the Batch Coding unit where the Batch Code, Manufacturing date etc. is printed on the Foil.

Batch coding unit:

The left hand foil before being drawn by the sealing rollers passes through the batch coding unit where the batch code, manufacturing date etc is printed on the foil.

Cutting System:

The Packed and sealed Strip from the Sealing Roller passes through the Brush and Slitter Shaft which cuts the Strips vertically. These vertically cut strips then passes through the Cam operated Cutter Assembly which Cuts the Strips Horizontally into the desired Strip Length. The desired Strip Length can be achieved by using the appropriate Cutting Gears and Toe Cams as per the pre defined Calculations

7.0 REASON FOR QUALIFICATION:

- New equipment in packing line.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

Packing line.

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
- Calibration of all critical Components of Equipment
- Preparation of SOP for Operating & Cleaning of Strip Packing Machine
- Preparation of SOP for Preventive Maintenance of Strip Packing 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 operating & Cleaning of Strip Packing Machine
- SOP for Preventive Maintenance Strip Packing 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 Products:

Objective:

- To verify the performance of equipment in the range of operational parameters established in Operational Qualification Activity.
- To establish documented evidence that the Strip Packing Machine is performing consistently and the result of all test parameters meet the pre – defined acceptance criteria of sifted products.

11.2.1 Checks:

- Knurling Uniformity
- Sealing Temperature
- Leak Test
- Wrinkles
- Pin Holes
- Coding Imprint
- Cutting Edges
- Localized Overheating
- Discoloration of Strip

11.2.2 Method:

- Install product specific change parts and foil in the machine.
- Load the product in the hopper of machine
- After attaining the required temperature perform initial run of machine without product to verify formed strip packs initially.
- Perform packing of product using machine as per the product specific parameters of the machine.
- Perform checks on the packed strips.
- Record the observations for all the checks in the report.

11.2.3 Acceptance Criteria:

S.No.	TEST PARAMETER	ACCEPTANCE CRITERIA
1.	Knurling Uniformity	Should be Uniform
2.	Sealing Temperature	Should be within the range specified in BPR
3.	Leak Test	No pocket of strip pack should show sign leakage in the test
4.	Wrinkles	Should be absent
5.	Pin Holes	Should be absent
6.	Coding Imprints	Should be clear & legible
7.	Cutting Edges	Should be Uniform
8.	Localized overheating	Should be absent
9.	Discoloration of strip	Should be absent

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.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of performance using Drug product.

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.

The following references are used to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition/March 2001.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.

- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.

14.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Operation and Maintenance Manual.

15.0 NON COMPLIANCE:

- All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED 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:

Sr.	:	Senior
Asst.	:	Assistant
No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices

EU : European Union

QA : Quality Assurance

IQ : Installation Qualification

mm : Millimetre

Amp. : Ampere