PERFORMANCE REQUALIFICATION PROTOCOL FOR BLISTER PACKING MACHINE (……..BLOCK) EQUIPMENT ID: ……

DATE OF REQUALIFICATION	
SUPERSEDES PROTOCOL NO.	

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

PROTOCOL CONTENT

1.0 PROTOCOL PRE -APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To establish documented evidences that the Equipment is performing as per the predetermined operational parameters and that it gives results within the predetermined acceptance criteria.
- To demonstrate that the system is operating reproducibly and consistently within its operating range.
- To confirm the suitability of the established Standard Operating Procedures for all routine activities associated with the equipment.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Requalification for the Blister Packing Machine serving Packing area at …….
- This Protocol will define the methods and documentation to be used for requalification of the **Blister Packing Machine (ID No.: ……).**

4.0 RESPONSIBILITY:

The Validation Team, 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, Review, Approval and Compilation of the Performance Requalification Protocol cum Report. • Co-ordination with Quality Control, Production and Engineering Departments to carryout Performance Requalification Activities. • Monitoring of Performance Requalification Activities.
Production	• Review of Protocol cum Report before and after execution. • To co-ordinate and support to other departments for conducting Performance Requalification Activity.
Engineering	• Review of Performance Requalification protocol for correctness, completeness and technical excellence. • Review of protocol cum report after execution. • Trouble shooting for problems (if occurred during execution).
Quality Control	• Review of Protocol cum Report before & after execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	BLISTER PACKING MACHINE
Manufacturer's Name	
Location of Installation	Packing Area
Equipment ID No.	

6.0 SYSTEM DESCRIPTION:

The blister packing machine is used to perform primary packaging operation of solid dosage forms. The blister packing operation includes:

1. **Blister formation:** It includes heating of PVC\PVDC foil at the blister forming station by heated die and formation of blister by suction of foil by applied vacuum inside the die.
2. **Filling of Product in the formed blister:** It includes passage of units of product to be packed from hopper to the empty blister through guide track.
3. **Overprinting on the base foil:** It includes movement of base foil from the close proximity of drum having attached stereo.
4. **Sealing of formed blister:** It is done by heating of base foil at the blister sealing station by the heated drum and then sealing of blister containing foil with base foil by compression with heated base foil.

On the basis of processing the machine can be divided as:

1. Blister forming station
2. Feeding station
3. Sealing station
4. Overprinting station
5. Embossing & perforation station
6. Cutting station

7.0 REASON FOR REQUALIFICATION:

Requalification is required as per requalification schedule. Requalification shall be performed according to detailed written procedures given in the protocol, with the original validation parameters and limits used as the evaluation criteria. The requalification studies shall be documented in detail and results of studies shall be compared to the original validation results and evaluated to the same extent. If the results are satisfactory, the system shall be certified. If the results are not satisfactory the modified system shall require new validation studies.

8.0 SITE OF STUDY:

Packing Area.

9.0 FREQUENCY OF REQUALIFICATION:

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

10.0 NON COMPLIANCE:

- In case of any deviation observed during Performance Requalification, inform to Head QA for necessary action.
- Document the details of deviation in 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.

11.0 PERFORMANCE REQUALIFICATION TESTS AND CHECKS

Performance Requalification shall be performed to establish documented evidences for the repeatedly and consistently working of the Blister Packing Machine within its predetermined operational range so as to meet the predefined acceptance criteria.

The performance requalification activities include steps:

1. Operating of Blister Packing Machine to perform packing of different products with their predetermined operational parameters and
2. Evaluation of packed products with their predefined specifications and acceptance criteria.

11.1 TEST REQUIREMENTS:

1. Tachometer
2. Leak test apparatus
3. Thermometer & sensor
4. Product batch size.

11.2 PROCEDURE:

1. The test should be carried out at predetermined operational parameters.
2. Load the Blister Packing Machine with product & packaging materials.
3. Switch "ON" the machine & operate as per SOP at different operational speed.
4. Set & run the machine as per the parameters mentioned in the BPCR.
5. Perform checks for parameters mentioned in the BPCR and record the observations in annexure.

12.0 REFERENCES:

The Principle Reference are 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 additional 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

13.0 DOCUMENTS ATTACHED:

- Calibration Certificate
- QC Raw Data

14.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

All deviations, non conformances and out of specification results obtained shall be investigated in accordance with corresponding SOPs and documented in the requalification report.

15.0 CHANGE CONTROL, IF ANY:

Details of change controls initiated during the re-qualification activity, shall be documented in the requalification report.

16.0 ABBREVIATION:

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	:	Millimeter
Amp.	:	Ampere
RPM	:	Revolutions Per Minute
Min	:	Minute
mg	:	Milligram
min.	:	Minimum
Max.	:	Maximum
Wt.	:	Weight
Tabs	:	Tablets
Avg.	:	Average
BPM	:	Blister Packs Per Minute