PERFORMANCE QUALIFICATION PROTOCOL FOR CHECK WEIGHER MACHINE

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

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PROTOCOL CONTENTS

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1.0 PROTOCOL 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)			

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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 Check Weigher Machine installed in **Packing Area**.
- This Protocol will define the methods and documentation used to qualify the Check Weigher Machine for PQ.

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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	• Initiation, 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.
Engineering	• Reviewing of Performance Qualification protocol for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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5.0 EQUIPMENT DETAILS:

Equipment Name	Check Weigher Machine
Equipment	
Manufacturer's Name	
Supplier Name	
Machine Serial No.	
Model	
Location of Installation	Packing Area

6.0 SYSTEM DESCRIPTION:

The checkweigher contains display conveyor belt control box automatic sensor for over & underweight variation other machine signal rejection foreign product rejection

The checkweigher consists of following Parts:-

- Infeed conveyor
- Photosensor/reflector
- Weighing conveyor
- Display
- Control box
- Power switch
- Rejector (option)
- Rejector conveyor (option)

7.0 REASON FOR QUALIFICATION:

- New equipment in Packing Area.
- 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 Area.

9.0 FREQUENCY OF QUALIFICATION:

- Once in 2 year

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- 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:

10.1 Training: The Training for the entire concerned person shall be provided and record shall be attached with the qualification report.

10.2 Verification of Documents:

Record the observations for documents in the below mentioned table.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date
1.	Executed and approved Design Qualification document			
2.	Executed and approved Installation Qualification document			
3.	Executed and approved Operational Qualification document			
4.	SOP for operating & Cleaning Of Check Weigher machine			
5.	SOP for Preventive Maintenance Of Check Weigher machine			

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

……

……

……

Reviewed By
Manager QA
Sign/Date: ……

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11.0 TESTS AND CHECKS:

11.1 TEST OF WEIGHT VERIFICATION:

A) OBJECTIVE:

The objective of Check weigher Machine is used for online weight checking of vials after filling and capping before labeling at three piece line and also checks the empty vials and missing dropper from the vials.

B) EQUIPMENT / INSTRUMENT USED:

Filled vials

C) METHOD APPLIED:

a) The test should be carried out initial, middle & end of triplicate batch for each pack size of vial.

b) Switch "ON" the machine & Operate as per SOP.

c) Collect 10 Filled vials from the turn table at initial, middle & end stage of batch.

d) Liquid filled & Dropper fixing with the vials load on the conveyor belt.

e) Passed the Filled vials through check weighers Machine.

f) Perform the test for 3.0 ml, 5.0 ml, & 10 ml pack size vials.

g) Performance Qualification test should be perform at Minimum, Optimum & Maximum speed and observation Record in Performance Qualification Report.

D) ACCEPTANCE CRITERIA:

Each filled vials weight should within specified limit as per particular pack size.

E) RESULT RECORDING:

Record the results in the performance Qualification report

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12.0 CHECKLIST OF ALL TESTS AND CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol to be executed and consisting of following tests.

TESTS OR CHECKS	Executed (Yes/No)	Remark
Test of weight verification for 3.0 ml		
Test of weight verification for 5.0 ml		
Test of weight verification for 10.0 ml		

Checked By
Production
Sign/Date: ……

Verified By
Quality Assurance
Sign/Date: ……

Inference:

……

……

……

Reviewed By
Manager QA
Sign/Date: ……

13.0 REFERENCES:

- 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:

- Any Other Relevant Documents.

15.0 NON COMPLIANCE:

- If any discrepancies or Non-compliance observed during Performance Qualification, it shall be immediate report to User Department Head & QA head.
- Note down the Non-Compliance with proper justification and mentioned simultaneously in Performance Qualification Report also.

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 properties of product & 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 properties of product & prepare final conclusion.

18.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
CWM	:	Check Weigher Machine
ID.	:	Identification Number
Ltd.	:	Limited
No.	:	Number
PPQ	:	Performance Qualification Protocol
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure