OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

The purpose of this document is to ensure operational qualification compliance of the equipment

PREPARED BY:

NAME AND DESIGNATION	SIGNATURE	DATE

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

APPROVED BY:

DEPARTMENT	NAME AND DESIGNATION	SIGNATURE	DATE

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1.0 SCOPE:

2.0 OBJECTIVE:

a. The objective of this Protocol is to define the requirements for Operation of the equipment designated: CHECKWEIGHER CW-1200

b. The purpose of this Protocol is to ensure that the equipment Operation meets the Acceptance Criteria. The Acceptance Criteria are when the actual results meet the expected results. If the acceptance criteria are met, a task report must be written summarizing the actual results.

3.0 ASSUMPTIONS, EXCLUSIONS AND LIMITATIONS

Assumes that the Installation Protocol as adhered to during Installation Protocol was generated and completed to required standards.

Any section that does not comply or does not successfully operate shall be rectified before proceeding with the Operation Qualification Protocol.

Each section relies on the preceding ones being successfully Installed and Successfully operating for the Protocol to be valid.

4.0 RESPONSIBILITIES

A. PHARMADEVILS PVT LTD's Responsibilities:

To develop and provide OQ protocol.
Further, if a representative is to execute the OQ protocol:

To complete the requirement of the OQ Protocol once approved By CUSTOMER.

To ensure that any deviations are reported, corrected and retested.

To write a final report summarizing the OQ results Demonstrating the ability to meet the acceptance criteria.

It is understood that …… is only providing to customer information and technical support on …… machine. It is entirely Customer's responsibility to obtain any internal and external approvals, compliances, certifications, and make suitable regulatory submissions and / or other submissions. ……. does not assume any liability for this or other reports / protocols.

Customer's Responsibilities:

To review and approve the OQ Protocol.
TO review and approve the final report (if generated by Pharmadevils Pvt Ltd).
To react to any deviation(s) deriving from the OQ protocol.

It is understood that Pharmadevils Pvt Ltd is only providing to customer information and technical support on Pharmadevils Pvt Ltd machine. It is entirely Customer's responsibility to

obtain any internal and external approvals, compliances, certifications, and make suitable regulatory submissions and / or other submissions. Pharmadevils Pvt Ltd does not assume any liability for this or other reports / protocols.

5.0 PROCESS DESCRIPTION:

Point	Description
A.	Before operating the machine ensure that the Equipment is free fromany Foreign particles ensure cleaning of the machine.
B.	Ensure that the recommended power supply and Air supply is available to the machine.
C	Ensure that the equipment is dully calibrated on the due date.
D.	Ensure that the conveyor belt is centrally aligned and is leveled & locking nuts are properly tightened.
E.	Allow some time for the machine to settle down after switching ON.
F.	Ensure rejection mechanism is functioning properly
G.	Pass some Overweight Samples and ensure the detection and rejection of the same.
H.	Pass some Underweight Samples and ensure the detection and rejection of the same.

5.0 PROCESS DESCRIPTION:

Point	Description
I.	Pass some accepted samples and ensure that they are not getting rejected.
J.	Pass some Overweight Samples and ensure the detection and rejection of the same.
K	Pass some Underweight Samples and ensure the detection and rejection of the same.
L.	Adjust Delay Setting to ensure proper rejection of Over & Under weight product. Once set do not alter the settings unless rejection does not occur properly.
M.	Repeat points I to K. for at least 10 time's until repeatability is confirmed.
N.	Repeat all the above points after every shift to ensure proper working of the machine.
O.	After proper confirmation of all the above points the Checkweigher is now ready for On line application.

6.0 INSTALLATION RECORD

Date of Installation:	**Order No.:**
Equipment No.:	**Installation Protocol No.:**
Installed by:	**Verified by :**

Comments:

7.0 TESTING CRITERIA

7.1 INSTRUCTIONS

Read all notes for each steps before beginning the test steps. Verify and record verification of all critical operational functions. Challenge each of the control system and each sub system. Any function, system or subsystem that fails a particular challenge should be identified and corrected before proceeding to the next section of the testing criteria. Any modification to the equipment to enable compliance with the operation, process or Qualification Protocol must be documented and approved prior to completion of the challenged section. Any modification that has an effect to the operation of the equipment must be challenged. Each challenge will be generated and approved by each department. If any additional raw data is generated during the implementation of this Protocol, all raw data must be identified and included / referenced in the "Attachments" section of this Protocol.

7.2 ACCEPTANCE CRITERIA

The test will be considered failed if the actual test results do not correspond to the expected results as detailed at each test step. Each test step must be completed prior to proceedings to the following step.

7.3 Equipment Functions Cont'd

INSTRUCTIONS

Read all notes for each test steps before beginning the test step. Operate and verify correct operation of all machine functions as listed. All results must be as specified by this protocol. Performance deviations must be identified and corrected prior to completion of this section.

Set up the machine as per the instruction manual. Supply the equipment with appropriate product and containers. Once you are satisfied that the system runs, verify that the following tests can be performed.

Document all performance deviations. Include:

1. The reason for deviation.
2. The equipment function Step number
3. The action taken to rectify the deviation.
4. Retest after rectification of any problems.

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Record each machine set up variation on a separate
"…… Challenge Sheet"

Note: All set up sheets and challenge sheets are numbered consecutively each set up sheet should be accompanied by the appropriate sheet and included in the "Attachments" section of this Protocol.

QUALIFICATON ATTACHMENTS

EQUIPMENT FUNCTIONS

CONTENTS

Sub section	Function Tested
A.	Rejection of Overweight material
B.	Rejection of Underweight material
C.	Acceptance of material without any weight deviation.

8.0 NOTES :

Any and all notes regarding the implementation of this protocol must be included in this section for further reference. Any requests to change the Operation Qualification Protocol after approval must be noted in this section

Date: _____

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Attachment:

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PHARMADEVILS CHALLENGE SHEET

Step	Challenged	Record	Verified	Signature
1.	Pass a sample of overweight sample with known weight and ensure that the sample is deflected by the reject mechanism and is placed in the reject bin.			
2.	Pass a sample of underweight sample with known weight and ensure that the sample is deflected by the reject mechanism and is placed in the reject bin.			
3.	Pass a sample of overweight sample with known weight with the product and ensure that the sample is deflected by the reject mechanism and is placed in the reject bin.			
4.	Pass a sample of underweight sample with known weight with the product and ensure that the sample is deflected by the reject mechanism and is placed in the reject bin. placed in the reject container.			
5.	Pass a known sample of product without any weight deviation I.e. product of accepted weight and ensure that the sample is not rejected by the reject mechanism.			

Comments:

COMMENTS :

9.0 ATTACHMENTS

Contents	Signature and Name	Date

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OQ CERTIFICATION

The data obtained from OQ has been reviewed and meets validation requirements. Proceed with PQ.

PERFORMED BY:

NAME AND DESIGNATION	SIGNATURE	DATE

PREWIEWED BY:

DEPARTMENT	NAME AND DESIGNATION	SIGNATURE	DATE