



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

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



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

PROTOCOL CONTENTS

S.No.	TITLE	PAGE No.
1.0	PROTOCOL PRE-APPROVAL	3
2.0	OBJECTIVE	4
3.0	SCOPE	4
4.0	RESPONSIBILITY	5
5.0	EQUIPMENT DETAILS	6
6.0	SYSTEM DESCRIPTION	6
7.0	PRE-QUALIFICATION REQUIREMENTS	7
8.0	CRITICAL VARIABLES TO BE MET	8-22
9.0	REFERENCES	23
10.0	DOCUMENTS TO BE ATTACHED	23
11.0	DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY	23
12.0	CHANGE CONTROL, IF ANY	23
13.0	REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY)	23
14.0	CONCLUSION	24
15.0	RECOMMENDATION	24
16.0	ABBREVIATIONS	25
17.0	POST APPROVAL	26



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

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)			



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

2.0 OBJECTIVE:

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Check Weigher Machine and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

3.0 SCOPE:

- The scope of this operational qualification protocol cum report is limited to qualification Check Weigher Machine installed in Packing Area.
- This Protocol will define the methods and documentation used to perform OQ activity the Check Weigher Machine
- Successful completion of this Protocol will verify that Check Weigher Machine meet all acceptance criteria and ready for Performance Qualification.



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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	<ul style="list-style-type: none">• Installation, Approval and Compilation of the Operational Qualification Protocol cum Report.• Co-ordination with Production and Engineering to carryout Installation Qualification.• Monitoring of Operational Qualification Activity.• Review & Pre Approval of Operational Qualification Protocol cum Report.
Warehouse	<ul style="list-style-type: none">• Review & Pre Approval of Operational Qualification Protocol cum Report.• To Co-ordinate and support for Execution of Qualification study as per Protocol.• Post Approval of Operational Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review & Pre Approval of Operational Qualification Protocol cum Report.• Co-ordination, Execution and technical support in Check Weigher Machine Installation Qualification Activity.• Responsible for Trouble Shooting (if occurs during execution).• Post Approval of Operational Qualification Protocol cum Report after Execution.



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

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

The check weigher consists of following Parts:-

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

6.1 PREPARATION FOR INSPECTION

- Ensure that the checkweighers is level and if necessary make adjustments.
- Allow the device to warm up for the specified time to guarantee stable measurements.
- Check weighers Machine at least 30 minules
- Use traceable standard weights of appropriate class for testing.
- Allow the standard weights time to adjust to the ambient temperature before testing.
- Ensure display reads zero when there is no load on the measurement conveyor.



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

6.2 STANDARD WEIGHTS USED FOR CALIBRATION

Use traceable standard weights and document the necessary information for management.

6.3 ADJUSTMENT

Use traceable standard weights to check and record measurement error before using the checkweighers. Before the error test confirm that zero is displayed when there is no load on the measurement conveyor. If measurement error is outside the acceptable range, make adjustments to the device and once again use standard weights to check and record measurement error. Refer to the instruction manual for information about adjustment.

6.4 REPEATABILITY TEST:

6.3.1 CONVEYOR IS STATIONARY

This test ensures that when the same load is measured with the practical methods under constant test conditions the results are the same. The standard weight used in this test is less than the maximum load.

First, record the indicator value when there is no load the measurement conveyor. Next place the standard weight in the centre of the measurement conveyor, record the value, and remove standard weight. Subtract the “zero” from the “weight” and record the standard deviation.

TEST PROCEDURE:

- Ensure there is no load on the measurement conveyor and take the zero.
- Record the value in the “No Load” column.
- Place the standard weight in the center of measurement conveyor and record the result in the “with Load” column. Remove the weight.
- Repeat step 2 and 3 time.
- Subtract “No Load” and “With Load” record the standard deviation. Check whether this value falls within the allowed error range and determine whether it passes or fails the test.



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6.3.2 CONVEYOR ACTIVE (SAMPLE)

This test ensures that when the same sample is measured with the same practical method under constant test conditions the results are the same.

The weight of the sample used in the test is less than the maximum load.

First, when there is no load on the measurement conveyor take the zero. Next place the sample in center of the measurement conveyor and record the result. Then turn on the conveyor. Measure and record the display value for the sample.

TEST PROCEDURE:

- Ensure there is no load on the measurement conveyor and take the zero.
- Place the sample in the center of the measurement conveyor and record the result in the “weight (stationary)” column.
- Turn on the conveyor
- Record the measurement result.
- Calculate the average, Maximum and Minimum values. Check that values fall within the allowed error range and determine whether it passes or fails the test.

6.5 CORNER LOAD ERROR TEST:

This test determines the measurement error for measurements taken away from the centre of the measurement conveyor. Divide the conveyor into 4 segments and use a standard weight of about 1/3 of the maximum capacity and measure from each segment.

TEST PROCEDURE:

- Take the zero
- Prepared the standard weight of about 1/3 of the maximum capacity of the device.
- Place the standard weight in the center of the measurement conveyor and record the weight.
- Next place the standard weight at position 2 and record the weight.
- Continue this process for positions 3 through 5.
- Calculate and record the deviation from the center “1” value.
- Checks pass if the deviation falls within the allowed range and fail if not.



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6.6 LINEARITY TEST:

This test involve placing successive standard weights in order up to a maximum weight on the measurement conveyor and recording the measurement value each time. Perform measurement for 2 or more points are described below.

- 2-point test: 1/2 weight and the maximum weight.
- 3 point test: 1/3 weight, 2/3 weight and the maximum weight.
- 4- point test 1/4 weight, 1/2 weight, 3/4 weight and the maximum weight

TEST PROCEDURE:

- Take the zero.
- Determine the number of measurement points and prepare the appropriate standard weights.
- Place the standard weight in the center of the measurement conveyor and record the value.
- Add another standard weight and record the display value. Repeat this until the maximum weight is reached.
- Calculation the deviation and check pass if it falls within the allowed error range and fail if it does not.



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7.0 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- DQ Protocol Cum Report
- IQ Protocol cum Report
- Draft SOP for operation & Cleaning of Reverse Laminar Air Flow
- Draft SOP for Preventive Maintenance of Dispensing Booth

7.1.1 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. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the OQ Protocol cum report.

7.1.2 Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

8.0 CRITICAL VARIABLES TO BE MET:

8.1 Verification of documents:

The results of any tests should meet the limits and acceptance criteria specified in the test documents.
Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	DOCUMENT NAME	DOCUMENT/SOP NO.	COMPLETED (YES/NO)	CHECKED BY (ENGINEERING) SIGN/DATE
1.	DQ Protocol Cum Report			
2.	IQ Protocol Cum Report			
3.	Draft SOP for operating & Cleaning of Check Weigher Machine			
4.	Draft SOP for Preventive Maintenance of Check Weigher Machine .			

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.2 Test Equipment Calibration:

Verification of Accuracy of Load Cell of Check Weigher Machine Use Calibrated Standard Weight.

STANDARD WEIGHT	CLASS	AUTHENTICATION NO.	DUE ON	OBSERVED BY (ENGINEERING) SIGN/DATE
500 gm				
1000 gm				
2000 gm				

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Production
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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

8.3 Operational and Functional Checks:

Operate the Check Weigher Machine as per Manufacturer's Manual/SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

8.3.1 Standard Weight use for Calibration:

STANDARD WEIGHT	CLASS	ID/Sr.No.	DUE ON	OBSERVED BY (ENGINEERING) SIGN/DATE
500 gm				
1000 gm				
2000 gm				

8.3.2 Adjustment

	BEFORE CALIBRATION	AFTER CALIBRATION	OBSERVATION (PASS/FAIL)
Standard Weight Measured Value (Max Weight)			

Acceptance Criteria: With in 0.1 gm of Standard Weight

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Quality Assurance
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8.3.3 Repeatability Test:

8.3.3.1 Conveyor is Satisfactory (Large Range):

S.No.	NO LOAD (A)	WITH LOAD (B)	OBSERVATION C= B-A	AVERAGE (C)	STANDARD DEVIATION (D)
1.					
2.					
3.					
4.					
5.					
Acceptance Criteria: Standard Deviation of C not More Than 0.18 gm					

8.3.3.2 Conveyor is Satisfactory (Small Range)

S.No.	NO LOAD (A)	WITH LOAD (B)	OBSERVATION C= B-A	AVERAGE (C)	STANDARD DEVIATION(D)
1.					
2.					
3.					
4.					
5.					
Acceptance Criteria: Standard Deviation of C not More Than 0.08 gm					

Checked By
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Inference:

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8.3.3.3 Conveyer Active (Sample)

COUNT	WEIGHT (IN MOTION)	MAXIMUM VALVE	MINIMUM VALVE	AVERAGE VALVE	STANDARD DEVIATION	STATUS (PASS/FAIL)
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

Standard Weight:gm

Acceptance Criteria :gm

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Production
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8.3.4 Corner Load Error Test:

Place	LARGE RANGE		SMALL RANGE	
	Value	Observation	Value	Observation
1				
2				
3				
4				
5				

Test load : 1000gm / 500 gm

Acceptance Criteria : Within ± 0.3 / ± 0.13 gm

Checked By
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Manager QA
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8.3.5 Linearity Test:

8.3.5.1 Large Range:

Weight	Display Value	Deviation	Observation (Pass/Fail)
0 gm			
500 gm			
1000 gm			
1500 gm			
2000 gm			

Acceptance Criteria : Within ± 0.3 gm

8.3.5.2 Small Range:

Weight	Display Value	Deviation	Observation (Pass/Fail)
0 gm			
100 gm			
200 gm			
300 gm			
400 gm			
500 gm			

Acceptance Criteria : Within ± 0.08 gm

Checked By
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Quality Assurance
Sign/Date:

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Manager QA
Sign/Date:



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8.4 Power Failure Verification:

ITEM	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Main Power shut down	Equipment stops in safe and secure condition		
Main Power Restored	Equipment can be restarted with no problems or adverse conditions.		

8.5 Alarm System Verification:

TEST	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) SIGN/DATE
Putting Manually low Volume Vial	Alarm should be Produce with Light		
Putting Manually High Volume Vial			
Putting Manually Standard Volume Vial			

Checked By
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Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Reviewed By
Manager QA
Sign/Date:



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8.6 Security Levels Verification.

CHECKS	ACCEPTANCE CRITERIA	OBSERVATION	OBSERVED BY (ENGINEERING) (SIGN/DATE)
Operator Level	Operator level should have access to process selection, Process start & stop in auto manual mode,.		
Supervisory Level	Supervisory level should have access to operator level all menu and in addition to that should have excess to set the process parameter ,batch information ,recipe preparation & Recipe upload.		
Manager Level	Manager level should excess to Supervisory level all menu and in additional to that should have excess to change the Password,		

**Checked By
(Production)**
Sign/Date:

**Verified By
(Quality Assurance)**
Sign/Date:

Inference:

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**Reviewed By
(Manager QA)**
Sign/Date:



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8.7 Challenge Test : Operate the Check Weigher Machine as per Manufacturer’s Manual/SOP and perform Challenge Test at Minimum speed, Optimum speed And maximum speed using 100 Vial of Each sample for test the following observation Recorded in Table

8.7.1 Test A (Speed / Capacity Verification): In this Test verify of Weighing Speed of Load Cell with respect to belt Speed

TRIAL	BELT SPEED	OUT PUT (PIECE/MIN)
1	15 m/min	
	15 m/min	
2	35m/min	
	35m/min	
3	52.5 m/min	
	52.5 m/min	
4	100 m/min	
	100 m/min	
5	120 m/min	
	120 m/min	

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Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:

Inference:

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Sign/Date:



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8.7.2 Test B: In this Test verify the Efficiency of load by using Challenge Vial. Each vial repeated 10 Time by Manually.

(a) Standard weight: Range : (..... gm togm)

Challenge Vial	Belt Speed (15 m/min)	Belt Speed (35 m/min)	Belt Speed (52.5 m/min)	Observation
Low Volume Vial				
High Volume Vial				
Dropper Missing Vial				
Cap Missing Vial				
Correct Volume Vial				

Acceptance Criteria : only pass with in range

(b) Standard weight: Range : (..... gm togm)

Challenge Vial	Belt Speed (15 m/min)	Belt Speed (35 m/min)	Belt Speed (52.5 m/min)	Observation
Low Volume Vial				
High Volume Vial				
Dropper Missing Vial				
Cap Missing Vial				
Correct Volume Vial				

Acceptance Criteria : only pass with in range



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(c) Standard weight:

Range : (..... gm togm)

Challenge Vial	Belt Speed (15 m/min)	Belt Speed (35 m/min)	Belt Speed (52.5 m/min)	Observation
Low Volume Vial				
High Volume Vial				
Dropper Missing Vial				
Cap Missing Vial				
Correct Volume Vial				

Acceptance Criteria : only pass with in range

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Production
Sign/Date:

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Quality Assurance
Sign/Date:

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Reviewed By
Manager QA
Sign/Date:



OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

9.0 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.

10.0 DOCUMENTS TO BE ATTACHED:

- Copy Of Draft SOP’s
- Any Other Relevant Documents

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR CHECK WEIGHER MACHINE

16.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practices
CWM	:	Check weigher Machine
DQ	:	Design Qualification
IQ	:	Installation Qualification
m	:	Metter
min	:	Minute
OQ	:	Operational Qualification
QA	:	Quality Assurance
SOP	:	Standard Operating Procedure
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization

17.0 PROTOCOL POST -APPROVAL:



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QUALITY ASSURANCE DEPARTMENT

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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)			