



PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

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



PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

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PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

1.0 REPORT 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)			



PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

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 scope of this report is limited for qualification of Check Weigher Machine installed in **Packing Area**.
- This report provides all the relevant information of the performance qualification activity, In-process observations write in Report



PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

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">• Initiation, Approval and Compilation of the Performance Qualification Report.• Co-ordination with Quality Control, Engineering and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.
Production	<ul style="list-style-type: none">• Review of Performance Qualification Report.• To co-ordinate and support Performance Qualification Activity.• Post Approval of Performance Qualification Report After Execution.
Engineering	<ul style="list-style-type: none">• Reviewing of qualification protocol for correctness, completeness and technical excellence• Responsible for trouble shooting (if occurred during execution).• Maintenance & preventive maintenance as per schedule.• Post Approval of Performance Qualification Report After Execution.



PERFORMANCE QUALIFICATION 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



PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

6.0 PRE – QUALIFICATION REQUIREMENTS:

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

6.2 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 (Production) Sign/Date	Verified By (QA) Sign/Date
1.	Executed and approved Design Qualification document				
2.	Executed and approved Installation Qualification document				
3.	Executed and approved Operational Qualification document				
4.	Approved Performance Qualification Protocol				
5.	SOP for operating & Cleaning of Check Weigher Machine				
6.	SOP for Preventive Maintenance Of Check Weigher Machine				

Inference:

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Reviewed By
Manager QA
Sign/Date:



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QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

7.0 TESTS AND CHECKS:

7.1 TEST OF WEIGHT VERIFICATION FOR 3.0 ML:

Date of test		Equipment ID No.	
Product Name		First Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Higher Limit
Vial Size / Fill Volume		Block / Area	

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
Speed of Conveyor (m/min.)				
Checked by (Production) Sign & Date				
Verified by (QA) Sign & Date				

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

.....

Reviewed By
Manager QA
Sign/Date:



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QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

Date of test		Equipment ID No.	
Product Name		Second Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Higher Limit
Vial Size / Fill Volume		Block / Area	

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
Speed of Conveyor (m/min.)				
Checked by (Production) Sign & Date				
Verified by (QA) Sign & Date				

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

.....

Reviewed By
Manager QA
Sign/Date:



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QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

Date of test		Equipment ID No.		
Product Name		Third Batch No.		
Std. Filled weight		Weight variation	Lower Limit	
			Higher Limit	
Vial Size / Fill Volume		Block / Area		

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
Speed of Conveyor (m/min.)				
Checked by (Production) Sign & Date				
Verified by (QA) Sign & Date				

**Checked By
Production
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:.....**

Inference:

.....

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



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PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

7.2 TEST OF WEIGHT VERIFICATION FOR 5.0 ML:

Date of test		Equipment ID No.	
Product Name		First Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Higher Limit
Vial Size / Fill Volume		Block / Area	

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
Speed of Conveyor (m/min.)				
Checked by (Production) Sign & Date				
Verified by (QA) Sign & Date				

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

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Reviewed By
Manager QA
Sign/Date:



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

Date of test		Equipment ID No.	
Product Name		Second Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Higher Limit
Vial Size / Fill Volume		Block / Area	

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			

Speed of Conveyor (m/min.)			
Checked by (Production) Sign & Date			
Verified by (QA) Sign & Date			

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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QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

Date of test		Equipment ID No.		
Product Name		Third Batch No.		
Std. Filled weight		Weight variation	Lower Limit	
			Higher Limit	
Vial Size / Fill Volume		Block / Area		

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
Speed of Conveyor (m/min.)				
Checked by (Production) Sign & Date				
Verified by (QA) Sign & Date				

**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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QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

7.3 TEST OF WEIGHT VERIFICATION FOR 10.0 ML:

Date of test		Equipment ID No.	
Product Name		First Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Higher Limit
Vial Size / Fill Volume		Block / Area	

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
Speed of Conveyor (m/min.)				
Checked by (Production) Sign & Date				
Verified by (QA) Sign & Date				

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

.....

Reviewed By
Manager QA
Sign/Date:



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

Date of test		Equipment ID No.	
Product Name		Second Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Higher Limit
Vial Size / Fill Volume		Block / Area	

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
Speed of Conveyor (m/min.)				
Checked by (Production) Sign & Date				
Verified by (QA) Sign & Date				

Checked By
Production
Sign/Date:

Verified By
Quality Assurance
Sign/Date:.....

Inference:

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Reviewed By
Manager QA
Sign/Date:



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

Date of test		Equipment ID No.	
Product Name		Third Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Higher Limit
Vial Size / Fill Volume		Block / Area	

Date	Vial No.	Initial (Weight in gm)	Middle (Weight in gm)	End (Weight in gm)
	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
Speed of Conveyor (m/min.)				
Checked by (Production) Sign & Date				
Verified by (QA) Sign & Date				

**Checked By
Production
Sign/Date:**

**Verified By
Quality Assurance
Sign/Date:.....**

Inference:

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.....
.....

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



PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

8.0 CHECKLIST OF ALL TESTS AND CHECKS:

This checklist is provided to ensure that all tests or checks required for this report have been executed.

TESTS OR CHECKS	EXECUTED [Y/N]	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:

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Reviewed By
Manager QA
Sign/Date:



PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

9.0 DOCUMENTS TO BE ATTACHED:

- Any Other Relevant Documents.

10.0 NON COMPLIANCE:

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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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PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

16.0 ABBREVIATIONS:

CWM	:	Check Weigher Machine
ID.	:	Identification Number
Ltd.	:	Limited
ml	:	Milliliter
No.	:	Number
PPQ	:	Performance Qualification Protocol
RPQ	:	Performance Qualification Report
SOP	:	Standard Operating Procedure
Vol	:	Volume



PERFORMANCE QUALIFICATION REPORT FOR CHECK WEIGHER MACHINE

17.0 REPORT POST – 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)			