



**PERFORMANCE QUALIFICATION REPORT
FOR
CHECK WEIGHER MACHINE**

PROTOCOL No.:

**PERFORMANCE QUALIFICATION
REPORT
FOR
CHECK WEIGHER MACHINE**

EQUIPMENT ID. No.	
LOCATION	Ointment Section
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



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**PERFORMANCE QUALIFICATION REPORT
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PROTOCOL No.:

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PROTOCOL No.:

1.0 REPORT PRE – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			



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



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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">• Preparation, Review Authorization and Compilation of the Performance Qualification Report.• Co-ordination with Quality Control, Engineering and Engineering to carryout Performance Qualification Activity.• Monitoring of Performance Qualification.• Post Authorization after the Compilation.
Production	<ul style="list-style-type: none">• Approval 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.



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5.0 EQUIPMENT DETAILS:

Equipment Name	Check Weigher Machine
Equipment	
Manufacturer's Name	A & D Instruments Pvt. Ltd.
Supplier Name	A & D Instruments Pvt. Ltd.
Machine Serial No.	
Model	
Location of Installation	Ointment Section

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	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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7.0 TESTS AND CHECKS:

7.1 TEST OF WEIGHT VERIFICATION:

7.1.1 FIRST BATCH AT MINIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2.	1			
	2			
	3			
	4			
	5			
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	7			
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7.1.2 AT OPTIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2.	1			
	2			
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7.1.3 AT MAXIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2.	1			
	2			
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7.2 SECOND BATCH :

7.2.1 AT MINIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1..	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2	1			
	2			
	3			
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PROTOCOL No.:

7.2.2 AT OPTIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2.	1			
	2			
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PROTOCOL No.:

7.2.3 AT MAXIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2.	1			
	2			
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7.3 THIRD BATCH :

7.3.1 AT MINIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2.	1			
	2			
	3			
	4			
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7.3.2 AT OPTIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
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PROTOCOL No.:

7.3.3 AT MAXIMUM SPEED:

Date of test		Equipment ID No.	
Product Name		Batch No.	
Std. Filled weight		Weight variation	Lower Limit
			Upper Limit
Type of Tube		Speed of conveyer	

Nozzle No.	Tube No.	Initial (Challenge Tube Weight in gm)	Middle (Challenge Tube Weight in gm)	End (Challenge Tube Weight in gm)
1.	1			
	2			
	3			
	4			
	5			
	6			
	7			
	8			
	9			
	10			
2.	1			
	2			
	3			
	4			
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	7			
	8			
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PROTOCOL No.:

7.4 Challenge Tube

7.4.1 Type I-A :

Date of Test		Challenge Tube Weight	
Product Name		Belt Speed	
Batch No.		Delay Time	
Equipment ID		Hold Time	
Range		Target Weight	

Challenge Tube from Nozzle-01	Observation of Weight (gm)	Machine Response	Challenge Tube from Nozzle-02	Observation of Weight (gm)	Machine Response
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		
8			8		
9			9		
10			10		

Correct Weight Tube

Acceptance Criteria: Challenge Tube Should be Rejected and correct tube should be Pass

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7.4.2 Type I-B :

Date of Test		Challenge Tube Weight	
Product Name		Belt Speed	
Batch No.		Delay Time	
Equipment ID		Hold Time	
Range		Target Weight	

Challenge Tube from Nozzle-01	Observation of Weight (gm)	Machine Response	Challenge Tube from Nozzle-02	Observation of Weight (gm)	Machine Response
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		
8			8		
9			9		
10			10		

Correct Weight Tube

Acceptance Criteria : Challenge Tube Should be Rejected and correct tube should be Pass

**Checked By
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Sign/Date:**

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

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**Reviewed By
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Sign/Date:**



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**PERFORMANCE QUALIFICATION REPORT
FOR
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7.4.3 Type I-C :

Date of Test		Challenge Tube Weight	
Product Name		Belt Speed	
Batch No.		Delay Time	
Equipment ID		Hold Time	
Range		Target Weight	

Challenge Tube from Nozzle-01	Observation of Weight (gm)	Machine Response	Challenge Tube from Nozzle-02	Observation of Weight (gm)	Machine Response
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		
8			8		
9			9		
10			10		

Correct Weight Tube

Acceptance Criteria : Challenge Tube Should be Rejected and correct tube should be Pass

**Checked By
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Sign/Date:**

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**PERFORMANCE QUALIFICATION REPORT
FOR
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PROTOCOL No.:

7.4.4 Type II-A :

Date of Test		Challenge Tube Weight	
Product Name		Belt Speed	
Batch No.		Delay Time	
Equipment ID		Hold Time	
Range		Target Weight	

Challenge Tube from Nozzle-01	Observation of Weight (gm)	Machine Response	Challenge Tube from Nozzle-02	Observation of Weight (gm)	Machine Response
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		
8			8		
9			9		
10			10		
Correct Weight Tube					

Acceptance Criteria : Challenge Tube Should be Rejected and correct tube should be Pass

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7.4.5 Type II-B:

Date of Test		Challenge Tube Weight	
Product Name		Belt Speed	
Batch No.		Delay Time	
Equipment ID		Hold Time	
Range		Target Weight	

Challenge Tube from Nozzle-01	Observation of Weight (gm)	Machine Response	Challenge Tube from Nozzle-02	Observation of Weight (gm)	Machine Response
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		
8			8		
9			9		
10			10		
Correct Weight Tube					

Acceptance Criteria : Challenge Tube Should be Rejected and correct tube should be Pass

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7.4.6 Type II-C :

Date of Test		Challenge Tube Weight	
Product Name		Belt Speed	
Batch No.		Delay Time	
Equipment ID		Hold Time	
Range		Target Weight	

Challenge Tube from Nozzle-01	Observation of Weight (gm)	Machine Response	Challenge Tube from Nozzle-02	Observation of Weight (gm)	Machine Response
1			1		
2			2		
3			3		
4			4		
5			5		
6			6		
7			7		
8			8		
9			9		
10			10		
Correct Weight Tube					

Acceptance Criteria : Challenge Tube Should be Rejected and correct tube should be Pass

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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
Weight Variation for 5.0 gm, 10, gm, 15 gm, 20.0 gm, & 30 gm Tube		
Challenge Test		

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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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14.0 CONCLUSION:

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**PERFORMANCE QUALIFICATION REPORT
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CHECK WEIGHER MACHINE**

PROTOCOL No.:

15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

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



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PROTOCOL No.:

17.0 REPORT POST – APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			