PERFORMANCE QUALIFICATION

FOR

MOISTURE ANALYZER

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

PERFORMANCE QUALIFICATION FOR MOISTURE ANALYZER

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1.0 Pre-Approval:

Signing of this Approval page of Performance Qualification Protocol No. ..... indicates agreement with the Performance Qualification approach described in this document. Should Modifications to the Performance Qualification become necessary; an addendum will be prepared and approved.

Written By	Signature	Date
Quality Control		

Checked By	Signature	Date
Production		
Quality Assurance		

Approved By	Signature	Date
Quality Assurance		
Plant Head		

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2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

- To verify the performance attributes of the ohaus *Moisture analyzer*, critical to serve the intended purpose.
- To document the observations for future reference.
- To provide documented evidence that the *ohaus Moisture analyzer* is operated and performed as per the Standard Operating Procedure.

2.2 Scope:

This protocol covers the Performance Qualifications of the Moisture Analyzer.

2.3 Responsibility:

The group comprising of representatives from each of the following departments shall be responsible for the overall compliance with this protocol:

- Production Department
- Quality Assurance Department
- Quality Control Department

The Production and In Process Quality Control shall be responsible for Performing as well as the checking of the Performance Qualification along with the Quality Assurance and recording data as per the procedures outlined in this protocol.

Quality Assurance shall collect all the test data and shall compile the results to make the reports of qualification studies.

The Reports shall be checked by Quality Assurance.

The Head Quality Assurance and Plant Head shall finally approve the Qualification report.

2.4 Requalification:

Performance Qualification to be repeated incase of

- Replacement of any major component.
- Major modification in the existing instrument.
- During monitoring if instrument. is found to be malfunctioning.
- Shifting of the instrument from one location to another.

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2.5 Instrument Identification:

The subjected instrument is identified as **Tablet Disintegration Tester**

Serial No. : _____

In-house Instrument No. : .....

Name of the Supplier : _____

Purchase Order No. : _____ Dated _____

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3.0 Performance Qualification:

3.1 Performance Qualification Procedure:

Perform the Qualification as per the following procedure.

3.1.1 Operate the instrument as per the SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.2.

3.1.2 Perform the External Calibration (Adjustment) with the External 50g weights and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.3 Perform the Temperature Calibration (Adjustment) with the Temperature Adjustment Kit and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.4 Perform the Calibration of the Instrument using Calibrated Weights for 50, 20, 10, 5, 2, 1, 0.5, 0.2, 0.1, 0.05 and 0.02g weights and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.5 Check repeatability measurement, five times with 0.5g weight and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.6 Check off-center error with 1.0 g weight and Record the observations of Qualification Test in Test Data Sheet of Section 3.3.

3.1.7 Report the deficiency from the specified function, if any in the section 3.4

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3.2 SOP Verification:

SOP No. :

Title :

Operate the instrument. as per the draft SOP and record the details given below:

Operated By : ……

Checked By : ……...

The operating personnel understand and follow the SOP description (Yes/No) :

Changes required in draft SOP (If any) :

_____

_____

_____

SOP to be revised (Yes/No) :

If yes, Review No. _____

Remarks: SOP Confirmed / Not Confirmed

Verified By :

Name: _____ Signature: _____ Date: _____

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3.3 Performance Qualification Test Data Sheet:

3.3.1 External Calibration (Adjustment) with External weight:

Type of the Calibration	Observations	Done By (Sign / Date)
Calibration (Adjustment) with External weights		

3.3.2 Temperature Calibration with Standard Temperature Kit:

Type of the Calibration	Observations		Done By (Sign / Date)
	Set Temp 80°C	Set Temp 160°C	
Temperature Calibration			

Verified By:

Name: _____ Signature: _____ Date: _____

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3.3.3 Calibration by External Weights

Details of the weight box _____

_____

_____

S.No.	Standard Weights	Actual Weight	Tolerance Limits	Observed Weights	Remarks	Done By
1.	50 g	g	± 0.050 g	g		
2.	20 g	g	± 0.020 g	g		
3.	10 g	g	± 0.010 g	g		
4.	5 g	g	± 0.005 g	g		
5.	2 g	g	± 0.002 g	g		
6.	1 g	g	± 0.001 g	g		
7.	0.5 g	g	± 0.001 g	g		
8.	0.2 g	g	± 0.001 g	g		
9.	0.1 g	g	± 0.001 g	g		
10.	0.05 g	g	± 0.001 g	g		
11.	0.02 g	g	± 0.001 g	g		

Verified By:

Name: _____ Signature: _____ Date: _____

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3.3.4 Repeatability measurement by 0.5 g weight

Details of the weight box _____

_____

_____

S.No.	Observed Weights	Remarks	Done By
1.			
2.			
3.			
4.			
5.			
Average			
SD			

Verified By :

Name : _____ Signature : _____ Date : _____

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3.3.5 Off Centre Error by 1.0 g weight

Details of the weight box _____

_____

_____

Position.	Observed Weights	Remarks	Done By
Centre			
Top			
Bottom			
Left			
Right			
Mean			

Verified By:

Name: _____ Signature: _____ Date: _____

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3.4 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write NA.

Description of deficiency and date observed:

_____
_____
_____
_____
_____

Person, responsible for corrective action and date assigned:

_____
_____
_____
_____

Corrective actions taken and date conducted:

_____
_____
_____
_____
_____
_____
_____

Conducted By: _____ Approved By : _____

Date : _____ Date : _____

Comments (if any):

_____

_____

Verified By:

Name: _____ Signature: _____ Date: _____

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4.0 Acceptance Criteria:

Performance Qualification shall be considered acceptable when all the conditions specified in various data sheets under section 3.0 have been met.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the instrument / component.

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5.0 Summary:

Checks	Observations Yes / No	Remarks (if any)
Whether the acceptance criteria of the protocol and specific checkpoints are met.		

5.1 Conclusion:

The ohaus Moisture analyzer bearing instrument no. ..... **is / is not** qualifying the Performance Qualification tests as per the Protocol No. ..... The Instrument **can / cannot** be used for the routine analysis.

5.2 Post-Approval:

Name	Signature	Date
Quality Control		
Quality Assurance		
Plant Head		

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6.0 Appendix:

6.1 Abbreviations and Definitions:

PQ	- Performance Qualification
mm	- Millimeter
Min	- Minutes
V	- Volt
Hz	- Hertz
Kg.	- Kilogram
cm	- Centimeter
N.A.	- Not Applicable
Sr.	- Senior
S.No.	- Serial Number
mV	- milli Volt
°C	- Degree Centigrade
AC	- Alternate Current
DC	- Direct Current
g	- Gram
RH	- Relative Humidity

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Acceptance criteria : The product, instrument., and / or process specifications and limits, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject.

Performance Qualification : The documented verification that all aspects of a facility, utility, or equipment that can affect product quality perform as intended meeting predetermined acceptance criteria?

Validation : Establishing documented evidence that a system does what it purports to do.

Revalidation : Repetition of the validation process or a specific portion of it