PERFORMANCE QUALIFICATION FOR AUTOMATED FRIABILATOR EF-2 (USP)

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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
Production		

Checked By	Signature	Date
Production		
Quality Assurance		

Approved By	Signature	Date
Quality Assurance		
Plant Head		

PERFORMANCE QUALIFICATION FOR AUTOMATED FRIABILATOR EF-2 (USP)

2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

- To verify the performance attributes of the *Automated Friabilator EF-2 (USP)* critical to serve the intended purpose.
- To document the observations for future reference.
- To provide documented evidence that the *Automated Friabilator EF-2 (USP)* is operated and performed as per the Standard Operating Procedure.

2.2 Scope:

This protocol covers the Performance Qualifications of the Automated Friabilator EF – 2 (USP).

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

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 -Quality Assurance and the 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.

2.5 Instrument Identification:

The subjected instrument is identified as **Automated Friabilator EF-2 (USP)**

Serial No. :

In-house Instrument No. :

Name of the Supplier : Electrolab

Purchase Order No. :

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.

3.1.2 Note the number of revolutions per minute by setting the count on 25, 100, 150 & 300 revolutions and record the observations in Section 3.2

3.1.3 Report the deficiency from the specified function, if any in the section 3.3

3.2 Performance Qualification Test Data Sheet:

3.2.1 Number of revolutions per minute:

S.No.	Standard Revolutions	Actual	Acceptance Criteria	Remarks
1	25		± 1	
2	100		± 1	
3	150		± 1	
4	300		± 1	

Verified By:

Name: _____ Signature : _____Date : _____

3.3 Deficiency (if any) and Corrective Action Report

If there is no deficiency, then write N. A.
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: _____

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 Automated Friabilator EF-2 (USP) Equipment 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 Assurance		
Plant Head		
Quality Assurance		

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
USP	-	United States Pharmacopoeia

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

PERFORMANCE QUALIFICATION FOR AUTOMATED FRIABILATOR EF-2 (USP)

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