OPERATIONAL QUALIFICATION OF AUTOMATED FRIABILATOR EF-2 (USP)

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1.0 Pre-Approval:

Signing of this Approval page of Operational Qualification Protocol No..... indicates agreement with the Operational Qualification approach described in this document. Should Modifications to the Operational 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		

OPERATIONAL QUALIFICATION FOR AUTOMATED FRIABILATOR EF-2 (USP)

2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

- To verify the operational attributes of *Automated Friabilator EF-2 (USP)*, critical to serve the intended purpose.
- To establish the suitability of the draft SOP prepared for the operation of System.
- To document the observations for future reference.

2.2 Scope:

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

2.3 Responsibility:

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

- Quality Control Department
- Quality Assurance Department
- Engineering Department

The Quality Control shall be responsible for checking the operations and recording data as per the procedures outlined in this protocol.

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

The Reports shall be checked by Production and Quality Assurance.

The post approval of the qualification shall be done by the Quality Assurance and plant Head.

2.4 Requalification:

Operational 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 Instrument is identified as ***Automated Friabilator Model EF – 2(USP)***

Serial No. :

In-house Instrument No. :

Name of the Supplier : **Electrolab**

Purchase Order No. :

3.0 Operational Qualification Procedure

1) A draft SOP shall be prepared on the basis of manufacturer guide / instrument manual for operation before the Qualification testing.

2) Prior to the Qualification test, the Personnel shall be trained by the Engineer from the Manufacturer / supplier on the operational features of the instrument. This training shall be recorded in Section 3.1.

3) The trained personnel shall carry out the Operational Qualification along with the Service Engineer, following the Procedures mentioned under Section 3.2.1 through 3.2.4 for Key Functionality and Safety Features. Record the observations of Qualification Test in Test Data Sheet of Section 3.2.1 through 3.2.4 Checkpoints designed for the purpose of OQ are also aimed at verification of these draft SOPs.

4) Operate the instrument as per the draft SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.3.

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

3.1 Training **Date:**

Title: Automated Friabilator EF-2 (USP)

Name of the Trainer(s): _____

S.No.	Name of the Trainee	Employee Number	Signature
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			

Signature of Trainer(s): _____

Date : _____

3.2. Key Functionality & Safety Features:

A. Purpose:

The purpose of this procedure is to demonstrate that the control panel and other manual operations (if any) of Automated Friabilator **(Equipment No.....)** function as specified by the manufacturer.

B. Testing:

1. Check all the displays on the panel are identified.
2. Turn on the power from the electrical panel.
3. Set the control(s) on the panel.
4. Verify functionality of each component on the panel against its Specified functions.
5. Observe and record the responses in the Test Data Sheet, under section 3.2.1.

3.2.1 TEST DATA SHEET (Confirmation of Services Connection):

S.No	Test Particulars	Specified Function	Observations	Checked By
1.	Switch 'ON' the instrument	The drums shall rotate and stop at the tablet loading position. Display shows 'Start"		
2.	Press all the keys on the front panel	Check for the buzzer beep		
3.	Set the desired time of revolution	Use the TIME key		
4.	Set the desired count of revolution	Use the COUNT key		
5.	Press ENTER	The desired set time or count will be registered		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No.	Test Particulars	Specified Function	Observations	Checked By
06	Press RUN / HALT Key	Drums will start rotating and the display will show elapsed time or count		
07	Completion of the test	Check for the buzzer sound and rotation of the drums in reverse direction for discharging the tablets into the trays		
		Test over shall be indicated by an audible beep and the display shall shows 'End'		

Verified By:

Name: _____ Signature: _____ Date: _____

3.3 SOP Verification:

Draft SOP No. : .....

Title : Automated Friabilator EF-2 (USP)

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): YES

Changes required in draft SOP (If any): _____

_____NO_____

_____

SOP to be revised (Yes/No): NO

If yes, Review No. _____

Remarks: SOP Confirmed / Not Confirmed

Verified By:

Name: _____ Signature: _____ Date: _____

3.4 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:

Operational 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.

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) **is / is** not qualifying the Operational Qualification tests as per the Protocol No..... The Instrument **can / cannot be** tested for its Performance Qualification as per Protocol No.....

5.2 Post-Approval:

Name	Signature	Date
Quality Control		
Plant Head		
Quality Assurance		

6.0 Appendix:

6.1 Abbreviations and Definitions

OQ - Operation Qualification
mm - Millimeter
Min - Minutes
V - Volt
Hz - Hertz
cm - Centimeter
N.A. - Not Applicable
S. No. - Serial Number
Sr. - Senior
mV - milli Volt
°C - Degree Centigrade
AC - Alternate Current
DC - Direct Current
g - Gram
RH - Relative Humidity
USP - United States Pharmacopoeia
SOP - Standard Operating Procedures

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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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.
Operational qualification	The documented verification that all aspects of a facility, utility, or equipment that can affect product quality operate as intended throughout all anticipated ranges.
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