INSTALLATION QUALIFICATION AUTOMATED FRIABILATOR EF-2 (USP)

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION OF AUTOMATED FRIABILATOR EF-2 (USP)

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1.0 Pre-Approval:

Signing of this Approval page of Installation Qualification Protocol No..... indicates agreement with the Installation Qualification approach described in this document. Should Modifications to the Installation Qualification become necessory, 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 provide an outline for the Installation Qualification of the instrument for static attributes to verify that:

- Each installed sub component complies with the instrument data sheets / specifications, agreed upon with the manufacturer.
- All supporting utilities are connected.
- The instrument is installed as per the laid down specifications.
- No unauthorized or unrecorded modifications have taken place.
- Required testing reports are available.
- A *draft* Standard Operating Procedures (SOP) have been identified and listed.

2.2 Scope:

This protocol covers the installation qualification of the Automated Friabilator EF – 2 (USP)

2.3 Responsibility:

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

- Quality Control Department
- Production Department
- Quality Assurance Department

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

The Quality Assurance shall be responsible for the final review of the qualification documents and its compliance to meet the acceptance criteria of the Installation Qualification protocol.

The summary report shall be approved by the Production and Quality Assurance.

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2.3 Requalification:

Installation Qualification to be requalified on:

- Replacement of major component of the Instrument with a new component.
- Any major modification in the existing Instrument.
- Shifting of the Instrument from one location to another.

2.4 System Description:

Checking the Friability is a very essential step during tablets compression. Friabilator gives us the idea about the product's performance during transportation. It saves from the danger of chipped tablets reaching the customer's hands.

Electrolab's microcontroller based EF-2 is designed to meet USP, IP, Ph. Eur. EF-2 offers a counter and timer mode of operation. The unique design allows filling and auto discharging of test samples without opening or removing the drums from its axis.

The unit supports ELECTROLAB AD Drums as well as "Abrasion" Drums. It has a unique front-loading system, which allows up to two drums to be loaded simultaneously on the instrument. The drums are designed to positively engage with the drive to prevent any slippage. Single or double drums can be held in position by a snap lock knob.

At the end of the test the test samples are automatically discharged into their individual trays. After discharging the samples, the drum positions itself automatically for loading new samples. The drums are rotated by a maintenance free stepper motor drive with a constant speed of 25 RPM. The specially designed drive provides a gentle starting and stopping of the drum.

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A 10° tilt of the drum with the bench top as per USP is provided to prevent any irregular tumbling of the test samples causing reproducibility problem due to shape and the size of the tablets. The 10° tilt no longer binds the tablets when lying next to each other which prevents them from falling freely.

The test can be performed in two modes –

(1) Time mode &

(2) Revolution Count mode

(1) Time mode: In this mode, the test duration is programmable. User can program the test duration from 1 Sec to 9 Hrs. 59 Min. & 59 Sec.

(2) Revolution Count Mode: In this mode, the number of rotations can be programmed from 1 to 99999 counts.

The values once programmed are retained in the memory of the instrument. The microcontroller, self validates the speed and revolution count.

The EF-2 has a unique power failure detection facility. If the power fails during the test, the remaining test is completed when the power supply is resumed.

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3.0 Instrument Specification:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Motor	DC Stepper Motor of 3.5 kg/cm Torque, 6 Volts
Speed	25 RPM Fixed
Speed Accuracy	± 1 RPM
Time Range	1 Sec to 9 Hrs 50 Min. and 59 Sec
Count Range	1 to 99999 revolutions
No. of Drums	Two
Type of the Drum	* ELECTROLAB AD Drum and Abrasion Drum (Optional)
Power Supply	220 / 230 V AC, 50 / 60 Hz, 20 VA 100 / 110 V AC, 50 / 60 Hz, 20 VA
Fuse Rating	T 160 mAmp (For I/P Supply as 220/230 VAC, 50/60 Hz) T 160 mAmp (For I/P Supply as 100/110 VAC, 50/60 Hz)
Size	L = 350 mm, W = 310 mm, H = 430 mm (Approx)
Weight	12 Kg (Approx.)

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4.0 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. :

5.0 Instrument Location:

Facility : Manufacturing

Area : Process Area

Room / Lab. Identification: In-process Quality Control

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6.0 Installation Qualification Procedure:

6.1 Inspection Checklist:

Instructions:

6.1.1 Check the Instrument physically for any damage and record the observation in the Data Sheet of section 6.2.

6.1.2 Identify the utility supplies required for instrument operation. Verify that utilities are as per the specification mentioned in the Check Point and record the observation in the Data Sheet of section 6.2.

6.1.3 Identify the critical accessories supplied with the instrument or installed on the utility supply line. Verify that instruments are as per the desired specifications.

6.1.4 Check the installation of instrument:

- To verify the proper assembly of the components as per the instrument manual. Record the installation location and verification of assembly in Test Data section 6.2.

6.1.5 Identify the SOPs and assign SOP Numbers, record the SOP Title and Number in Section No. 6.2.

6.1.6 Record the deficiency (if any) in section number 6.2 and report the details of action taken.

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Note:

1. *Record all the observations against the respective specifications, mentioned in the specific checkpoints, under section 6.2 (The specifications are extracted from the Purchase order / Manual / Manufacturer's Recommendations).*
2. *Incase of non-compliance, give the explanation / justification in the deficiency and corrective action report format under section 6.2.*
3. *When more than one unit of the same type exist, replicate the corresponding data sheet to match and uniquely identify each page.*
4. *Incase of multiple options; clearly identify the one, which has been supplied.*
5. *The calibration certificates of the instruments shall be traceable to National / International standards.*
6. *Define all technical terms and abbreviations in the appendix under section 10.0.*

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6.2 Installation Qualification:

6.2.1 Physical verification of the instrument / Environment

Objective: To verify that any physical damage of the instrument and Environmental condition for the operation of the Instrument.

S.No.	Test Particulars	Specifications	Observations	Acceptance Yes/No
Physical Verification				
1.	Check the Instrument for any damages.	There should not be any damages.		
Environmental Conditions				
1.	Room Temperature	15℃ to 30℃		
2.	Relative Humidity	45% to 70%		
3.	Away from the Sunlight	-		
4.	Free from Vibrations	-		
5.	No corrosive Gases	-		
6.	Free from excess dust and moisture	-		
7.	Stability of input power (± 10% of 230 v AC 50 Hz)	-		

Checked by (Engineering) _____ **Name** _____ **Sign.** _____ **Date**

Verified by (Quality Assurance) _____ **Name** _____ **Sign.** _____ **Date**

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6.2.2 Major Component Verification:

Objective: To verify that major components as identified below are complying as per the desired specifications.

S. No.	Name	Part No.	Qty. Supplied	Observations	Acceptance Yes/No
1	Basic Unit		1		
2	USP Drum Friability		2		
3.	Abrasion Drum (Optional)		-		
4.	Tablet Collection Tray		2		
5.	Drum Fixing Knob		1		
6.	Mains cord		1		
7.	Manual		1		

Checked by (Engineering) _____ **Name** _____ **Sign.** _____ **Date**

Verified by (Quality Assurance) _____ **Name** _____ **Sign.** _____ **Date**

6.2.3 Verification of Utility Supply:

Objective: To verify that necessary utility supplies required for instrument operation are as per the desired specification and connected properly.

S.No.	Utility	Specifications	Observations	Connected and Identified (Yes / No)
1.	Power	Single Phase, 230V ± 10% 50 Hz		

Note: *Power Supply to be checked with a Multimeter.*

	Name	Sign.	Date
Checked by (Engineering)			
Verified by (Quality Assurance)			

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6.2.4 Standard Operating Procedures (SOPs) Identification:

SOP's	Number	Title
Operation, Calibration and Cleaning		Automated Tablet Friabilator (USP) EF-2

Checked by (Engineering)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.5 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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7.0 Acceptance Criteria:

Installation Qualification shall be considered acceptable when all the conditions specified in various forms under section 6.0 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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8.0 Remarks (if any):

_____

_____

_____

_____

_____

_____

_____

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9.0 Summary:

Checks	Observations	Remarks
Whether acceptance criteria of the protocol and Specific check points are met.	Yes/No	

9.1 Conclusion:

The Automated Friabilator EF-2 bearing Equipment No. **is / is not** qualifying the Installation Qualification tests as per the Protocol No. ....., hence the instrument **can / cannot** be tested for its Operational Qualification as per Protocol No. .....

9.2 Post-Approval Signatures:

Name	Signature	Date

10.0 Appendix:

10.1 Abbreviations and Definitions

IQ	- Installation 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
gm	- Gram
RH	- Relative Humidity
UPS	- Uninterrupted Power Supply
Kg	- Kilogram
Hr.	- Hour
Sec	- Seconds
S.S.	- Stainless Steel
Nos.	- Numbers
mAmp	- Milli Amperes
Amp	- Amperes
Eq.	- Equipment
USP	- United States Pharmacopoeia
Ph Eur	- European Pharmacopoeia
IP	- Indian Pharmacopoeia

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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.
Installation qualification	:	The documented verification that all aspects of a facility, utility or equipment that can affect product quality adhere to approved specifications (e.g., construction, materials) and are correctly installed?
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.

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10.2 List of Documents:

1. Instrument manuals
2. Purchase Order Attached (Yes / No). If no, state Location.

   Purchase Order No. ..... Dated ..... is attached.
3. Calibration Certificates
4. Draft SOP No. SAP / 0