



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Cleaning, Operation and Calibration of Friabilator (Electrolab EF2)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the procedure for Cleaning, Operation and Calibration of Friabilator (Electrolab EF2) in production department.

2.0 SCOPE:

This procedure is applicable to Cleaning, Operation and Calibration of Friabilator (Electrolab EF2) used in production department.

3.0 RESPONSIBILITY:

Production: Technical Associate/Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance

Head QA: To ensure the compliance

4.0 PROCEDURE:

4.1 Cleaning:

4.1.1 Remove the acrylic drums by pressing the knobs provided.

4.1.2 Remove the tablet-collecting tray by pulling outside.

4.1.3 Dry-clean the equipment and acrylic drums using a dry lint free cloth.

4.2 Operation:

4.2.1 Ensure that the equipment is cleaned.

Check the current calibration status of the instrument before starting of friability checks.

4.2.2 Put the power supply ON.

4.2.3 After power is switched ON the drum will initialize itself to the loading position and the instrument will initialize and the display will show "START".

4.2.4 Setting of time:

4.2.4.1 Press the "TIME" button.

4.2.4.2 The display will show "0.00.00" on the screen or previous Time Values.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Cleaning, Operation and Calibration of Friabilator (Electrolab EF2)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 4.2.4.3 Enter 4 minutes and press the “ENTER” Key to register the value.
- 4.2.4.4 Take the sample quantity as given in the respective BMR.
Note: Remove any loose dust before weighing.
- 4.2.4.5 Load the weighed tablets in the slit provided in the drum.
- 4.2.4.6 Ensure that the Drum is locked properly.
- 4.2.4.7 Press RUN/HALT key to start the test.
- 4.2.4.8 The drum will start rotating.
- 4.2.4.9 The display will show elapsed Time.
- 4.2.4.10 When the test is over, ensure that the drum rotates in the reverse direction discharging all the test samples into the collection tray located below the drum.
- 4.2.4.11 Ensure that completion of test is indicated by audible beep.
- 4.2.4.12 The drum would now initialize itself to the loading position. Carefully slide the tray out and remove the loose dust from the test samples, i.e. dedust the test samples. After dedusting, weigh the test samples.
- 4.2.5 Setting of counts:**
- 4.2.5.1 Press the “COUNT” button.
- 4.2.5.2 The display will show “00000” on the screen or previous count Values.
- 4.2.5.3 Enter 100 counts and press “ENTER” key to register the value.
- 4.2.5.4 Follow the procedure in point no. 4.2.4.4 to 4.2.4.8.
- 4.2.5.5 The display will show elapsed count.
- 4.2.5.6 Follow the procedure in point no. 4.2.4.10 to 4.2.4.12.
- 4.2.6 Calculate the % friability as per the following formula and enter the same in BMR.
% of friability:
$$\frac{(\text{Initial weight} - \text{final weight})}{\text{Initial weight}} \times 100$$
- 4.2.7 To reset the instrument when in run, press the RESET key. The test is considered to be OVER and the test samples are unloaded into the tray and the instrument is initialize for new test.
- 4.2.8 **Note:**
- If the tablets having irregular tumbling then the Friabilator should be tilted at 10° with help of inclined legs of Friabilator.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Cleaning, Operation and Calibration of Friabilator (Electrolab EF2)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- If the power is failure in between operation, Repeat the same operation with fresh tablet.
- In case of any discrepancies observed, inform the department head and engineering department for corrective action.
- Do not use the Friabilator till the problem is rectified.

4.3 Calibration:

- 4.3.1 Operate the instrument as per point no. 4.2.1 to 4.2.3.
- 4.3.2 Set the revolution to 25 with numerical button on the panel.
- 4.3.3 Start the instrument and note down the number of revolution display and time taken by the friability using a calibrated stop watch and enter the values in annexure-I.
- 4.3.4 Set the revolution to 50,100 and repeat the above operation. The number of revolution shall be counted for the set value of 50 and 100 respectively.
- 4.3.5 Record the number of revolution display and time taken in format as per the Annexure-I.
- 4.3.6 Calculate the revolution per minute by dividing the number of revolution display by time taken.
- 4.3.7 Acceptance criteria: 25 ± 1 Revolution per minute
- 4.3.8 Affix calibration status label duly filled and signed on the equipment.
- 4.3.9 If the instrument is out of calibration, put an “OUT OF CALIBRATION” tag, and proceed as per SOP.
- 4.3.10 **Frequency:**
- The frequency of calibration of friability test apparatus is Monthly ± 3 days.
 - If any breakdown, after rectification re-calibrate the friability apparatus.

5.0 ANNEXURE (S):

Annexure – I: Calibration record of Friabilator (Electrolab EF2)

6.0 REFERENCE (S) :

SOP: Preparation, Approval, Distribution control, revision and destruction of Standard operating Procedure (SOP).



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: SOP for Cleaning, Operation and Calibration of Friabilator (Electrolab EF2)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

SOP: Handling of Out of calibration of Instruments.

GTP : Friability test.

USP <1216>/BP Appendix XVII G1/Ph. Eur. 2.9.7 /IP 2.5.5

7.0 ABBREVIATION (S) /DEFINITION (S) :

SOP: Standard Operating Procedure.

BMR : Batch Manufacturing Record

USP : United State Pharmacopoeia

BP :British Pharmacopoeia

Ph. Eur. :European Pharmacopoeia

IP : Indian Pharmacopoeia

RPM :Revolution Per Minute

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S)FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---