



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Quality Control	<b>SOP No.:</b>
<b>Title:</b> Operation and Calibration of Tablet Friability Test Apparatus	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**1.0 OBJECTIVE:**

To lay down a procedure for Operation and Calibration of “Tablet Friability” Test Apparatus.

**2.0 SCOPE:**

This procedure is applicable to operation and calibration of “Tablet Friability” test apparatus in the Quality Control Department.

**3.0 RESPONSIBILITY:**

Officer, Executive– Quality Control Department  
Head– Quality Control Department

**4.0 DEFINITION(S):**

NA

**5.0 PROCEDURE:**

**Make: Electrolab, Model: EF-2**

**5.1 Operation:**

- 5.1.1 Ensure that instrument is clean and free from dust.
- 5.1.2 Switch on the mains.
- 5.1.3 Reset the instrument with the help of keyboard on the instrument.
- 5.1.4 Weigh tablets equivalent to 6.5 g if the average of tablet is less than 650 mg & take 10 tablets if the average weight of tablet is equal or greater than 650 mg.
- 5.1.5 Close the drum.
- 5.1.6 Set the time of 4 minutes (240 seconds) with the help of numerical key and enter it, or
- 5.1.7 Similarly set the rotation count (100) with the help of numerical key and enter it.
- 5.1.8 Press the run / halt key of the instrument, instrument will start, if you want to halt in between running, press run / halt key, and to start again press run / halt key.



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5.1.9 After completing 100 rotations instrument will stop by displaying end on display screen with beep sound.

5.1.10 Tablets will automatically get transferred in tray which is connected with instrument by rotating clockwise and anticlockwise.

5.1.11 Collect the tablets from the tray, blow to remove the powder.

5.1.12 Weigh the tablets and calculate the friability in percentage as under,  
$$\frac{\text{Weight of tablets before friability} - \text{Weight of tablets after friability}}{\text{Weight of tablets before friability}} \times 100$$

5.1.13 Clean the drum and instrument and also put off main switch.

5.1.14 Record the use of instrument in the instrument log book.

**5.2 Calibration:**

5.2.1 Operate the instrument as mentioned in the above procedure.

5.2.2 Count the rotation per minute for three times.

5.2.3 Check time with the help of Stopwatch i.e. 240 seconds (4 minutes) for three times.

5.2.4 Tolerance - for Rotation 100 + 4 rotation & for Time + 10 seconds

5.2.5 Frequency - Monthly

5.2.6 Fill the calibration status on metallic calibration label of the instrument, record the calibration results in annexure-I

5.2.7 If instrument is out of calibration, affix "UNDER MAINTENANCE" label on the instrument and call for service engineer.

**5.3 Cleaning:**

5.3.1 Clean the drum properly with cotton.

**5.4 Precaution:**

5.4.1 Instrument free from any type of moisture.

5.4.2 Lock the drum properly.

**6.0 ABBREVIATION(S):**

QCD – Quality Control Department



**PHARMA DEVILS**  
QUALITY CONTROL DEPARTMENT

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SOP – Standard Operating Procedure

NA – Not Applicable

g - gram

**7.0 REFERENCE(S):**

NA

**8.0 ANNEXURE(S):**

ANNEXURE –I : Calibration Record of Friability Test Apparatus

**9.0 REVISION CARD:**

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION



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**ANNEXURE I**

Calibration Record: Friability Test Apparatus			
<b>Location</b>		<b>Model No.</b>	
Make	Electro lab	Identification No.	
Calibration Done On		Calibration Due On	
<b>Reference SOP No.:</b>			Page No. : 4 of 1

S. No.	Rotation	Observed Rotation (Limit 100 + 4)	Set time (In Second)	Observed Time (In Second) (Limit 240 + 10)	Remarks
1.	100		240		
2.	100		240		
3.	100		240		

**Remarks:** The Instrument Calibration **Complies / Does Not Comply.**

<b>Calibrated By :</b>		<b>Checked By :</b>	
<b>Date:</b>		<b>Date:</b>	