



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning, Operation and Calibration of Friability Test Apparatus	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for cleaning, operation and calibration of friability test apparatus.

2.0 SCOPE:

This procedure is applicable to cleaning, operation and calibration of friability test apparatus used in production department.

3.0 RESPONSIBILITY:

Officer/ Executive Production: Operation and Calibration

Head Production : SOP Compliance

IPOA : Operation and calibration

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Cleaning

5.1.1 Switch OFF the main Supply.

5.1.2 Remove the acrylic drums by pressing the knobs provided and remove its covers.

5.1.3 Remove the tablet-collecting tray by pulling outside.

5.1.4 Dry-clean the equipment; tablet collecting tray, acrylic drums and its covers using a dry lint free duster.

5.1.5 Clean the tablet collecting tray acrylic drums and its covers with the help of wet lint free duster followed by dry lint free duster.

5.1.6 Fix the drums with cover to the equipment and place the tablet collecting trays beneath the drums.

5.2 Operation

5.2.1 Ensure that the equipment is cleaned.

5.2.2 Put the power supply ON.

5.2.3 Display will show "START".

5.2.4 Setting of time

5.2.4.1 Press the "TIME" button.

5.2.4.2 Set the time to 4 minutes from the numerical button on the panel.

5.2.4.3 Press the "ENTER" button, then display will show "00.00" on the screen.

5.2.5 Setting of counts

5.2.5.1 Press the "COUNT" button.

5.2.5.2 Set the count to 100 from numerical button on the panel.



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- 5.2.5.3 Press the ‘ENTER’ button, then display will show ‘00000’ on the screen.
- 5.2.6 Take the initial weight of the tablets. .
- 5.2.7 Load the weighed tablets in the slit provided in the drum.
- 5.2.8 Switch on the apparatus.
- 5.2.9 After completion of 100 rotations, the equipment will stop and the tablets go to the tray provided automatically.
- 5.2.10 Take out the intact tablets and remove any loose dust with help of soft brush and then weigh it.
- 5.2.11 Calculate the friability as per the following formula and enter the same in BMR.

$$\frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} \times 100$$

- 5.2.12 Put off the power supply.
- 5.2.13 Clean the equipment as per Cleaning procedure.
- 5.3 Calibration**
- 5.3.1 Set the count to 100 revolutions from the numeric buttons on the panel.
- 5.3.2 Count the number of revolutions for each minute manually by using calibrated stopwatch or with calibrated digital tachometer.
- 5.3.3 Start the machine by pressing ‘start’ button and count the number of revolutions in one minute i.e. for 25 rotations.
- 5.3.4 After completion of one minute press run/halt button to stop the machine.
- 5.3.5 Record the number of revolutions in one minute in Annexure – I.
- 5.3.6 Restart the machine by pressing run/halt button for further one minute (i.e. for 50 counts). Stop the machine by pressing run/halt button after completion of one minute and record the number of revolutions for one minute in annexure -I
- 5.3.7 Repeat the step 5.3.6 for 75 and 100 revolutions.
- 5.3.8 Put the date of calibration and due date of calibration on the calibration tag affixed on the machine with sign and date.
- 5.3.9 In case of any discrepancies observed, affix the ‘UNDER MAINTENANCE’ status label, inform the department head and engineering department for corrective action.
- 5.3.10 Do not use the friability test apparatus till the problem is rectified.
- 5.3.11 After rectification, re-calibrate the friability test apparatus and enter the same in Annexure-I.



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Note: Repeat the same operation with fresh tablet if the power failure occurs in between the operation.

5.3.12 **FREQUENCY:** Once in a month

6.0 ABBREVIATION (S):

QA : Quality Assurance

SOP : Standard Operating Procedure

RPM : Revolutions Per Minute

7.0 RERERENCE (S):

7.1 Current BP

7.2 Labeling SOP

8.0 ANNEXURE (S):

ANNEXURE-I : Friability test apparatus calibration record

9.0 DISTRIBUTION:

9.1 **Master copy** : Quality Assurance

9.2 **Controlled copy (s)** : Production department, Quality Assurance

9.3 **Reference copy (s)** : Production department



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ANNEXURE I

FRIABILITY TEST APPARATUS CALIBRATION RECORD

INSTRUMENT : FRIABILITY TEST APPARATUS

MAKE & MODEL :

INSTRUMENT USED	IDENTIFICATION No.	CALIBRATION STATUS	
		Calibration Done On	Calibration Due On
STOP WATCH/ TACHOMETER			

EQUIPMENT ID NO. :

DATE OF CALIBRATION :

NEXT CALIBRATION DUE ON :

FREQUENCY OF CALIBRATION : MONTHLY

Set Revolution	No. of Revolution performed		LED Display at stop position	Revolutions per minute (Limit: 25 ± 1)
	Count	Time taken		
25				
50				
75				
100				

Remarks: The Instrument is calibrated and qualified/out of calibration and not qualified for use.

DONE BY:

CHECKED BY:

DATE:

DATE: