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|  | UNIVERSITY OF MALTA FACULTY OF MEDICINE & SURGERY PHARMACY DEPARTMENT | Ref. No. SOP/PD/314_01 |
| | STANDARD OPERATING PROCEDURE | |
| | FRIABILITY TESTER WITH ABRASION DRUM | |

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1. Scope

This Standard Operating Procedure (SOP) applies to the staff and students using the Friability Tester in the laboratories of the Pharmacy Department, University of Malta.

2. Objective

To describe the procedure for the operation and maintenance of the Friability Tester.

3. Definitions

- 3.1. **Abrasion Drum:** Consists of 12 standardised internal plastic baffles used to test the abrasion strength of the tablets.
- 3.2. **Friability/Abrasion Tester:** Consists of a drive unit that rotates a transparent plastic drum at a standard 25rpm.
- 3.3. **Friability Test:** Provides a standardised, reproducible method for measuring the tendency of a tablet to chip or powder when subjected to the mechanical stresses of the manufacturing, packaging and transportation processes of the tablet.


4. Responsibility

- 4.1. The members of the Department of Pharmacy (staff and students) are responsible for following this SOP.
- 4.2. The designated Laboratory Officer or Laboratory Assistant is responsible for ensuring that this SOP is followed.

5. Procedure

5.1. Operation

- 5.1.1. Connect the power cord to an appropriate electrical outlet.
- 5.1.2. Unscrew the locking nut to release the drum.
- 5.1.3. Brush any loose dust from the tablets to be tested.
- 5.1.4. Accurately weigh the tablets.
- 5.1.5. Load the tablets into the drum.

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- 5.1.6. Place the plastic cover over the drum.
- 5.1.7. Hold the cover firmly in place and slide the drum body onto the shaft.
- 5.1.8. Place the locking nut onto the end of the shaft.
- 5.1.9. Tighten the locking nut into position.
- 5.1.10. Turn the knob to the desired number of rotations.
- 5.1.11. Wait until the drum returns to a stationary position.
- 5.1.12. Remove locking nut.
- 5.1.13. Carefully remove the drum from the shaft.
- 5.1.14. Remove the tablets and brush away any loose powder from them.
- 5.1.15. Check for any obviously cracked, cleaved or broken tablets since this will indicate that the sample tablets have failed the friability test.
- 5.1.16. Reweigh the tablets.
- 5.1.17. Calculate the percentage of weight loss using the following formula:


$$\% \text{ weight loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100\%$$

5.2. Maintenance

- 5.2.1. Routinely check drums for signs of cracks or chips.
- 5.2.2. Inspect electrical connections for signs of corrosion and damage.
- 5.2.3. Immediately wipe any spills from the exterior of the equipment using a moistened clean cloth.
- 5.2.4. Clean drums thoroughly after each use using deionised water and dry with a soft cloth.

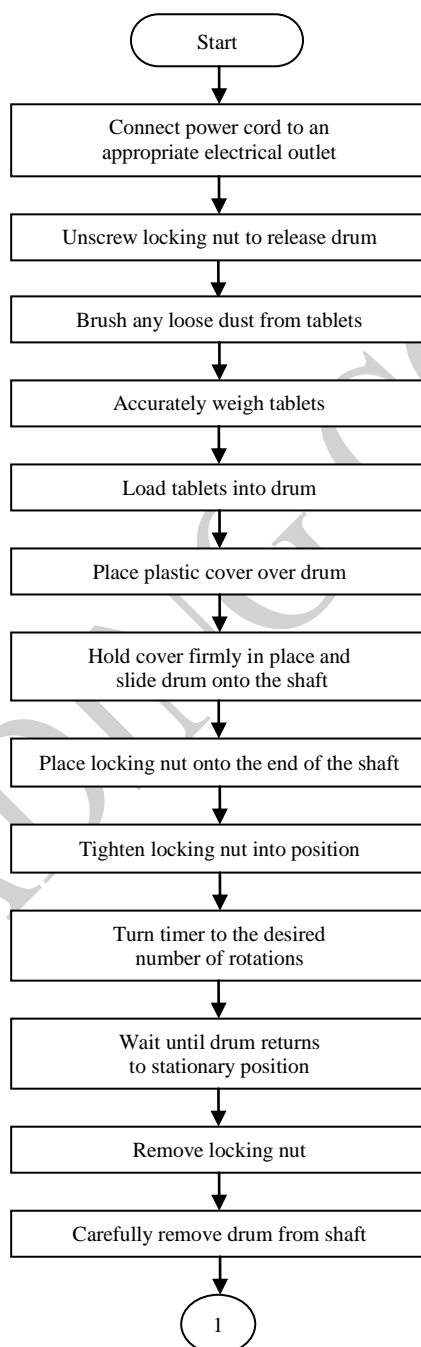
5.3. Average time taken to carry out Procedure

| Procedure Section | Average Time (mins) |
|--------------------|---|
| Operation | 14 (for one test with standard 100 revolutions) |
| Maintenance | N/A |

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5.4. Flow Charts

5.4.1. Operation





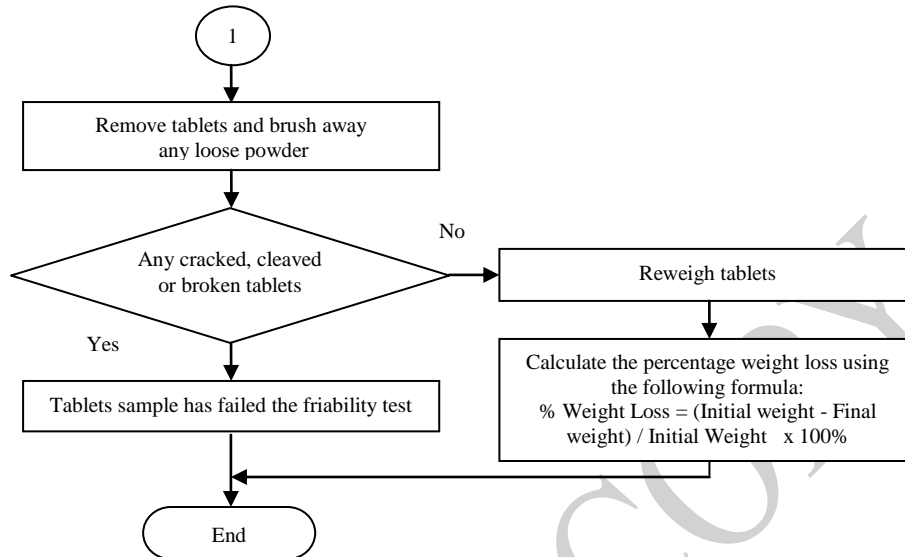
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PHARMACY DEPARTMENT


STANDARD OPERATING PROCEDURE

FRIABILITY TESTER
WITH ABRASION DRUM

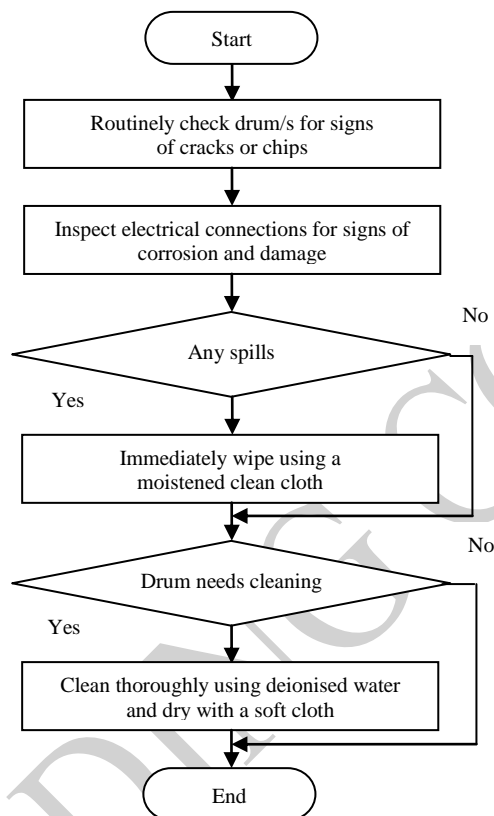
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5.4.2. Maintenance



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6. Precautions

- 6.1. Do not open the electrical compartment due to the risk of shock and allow only trained personnel to do so.
- 6.2. When tightening the locking nut, ensure that it is not overtightened since this can cause damage to the drum.
- 6.3. Do not use cleaning compounds containing ammonia or abrasive cleaners to clean the plastic drum since such compounds may damage plastic, causing it to crack and fracture.
- 6.4. For tablets with a unit mass equal to or less than 650mg, a sample of tablets corresponding as near as possible to 6.5g is to be used whilst for tablets with a unit mass greater than 650mg, a sample of 10 whole tablets is to be used.
- 6.5. According to the British Pharmacopoeia, 100 rotations are considered to be the standard number of rotations to be used for each test.
- 6.6. According to the British Pharmacopoeia, a maximum loss of mass not greater than 1.0 per cent is considered acceptable for most types of tablets.

7. References

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Huynh-Ba K, editor. Handbook of Stability Testing in Pharmaceutical Development. New York: Springer; 2009. p. 215-216.

Salman AD, Ghadiri M, Hounslow MJ editors. Volume 12 Particle Breakage. The Netherlands: Elsevier; 2007. p. 960-962.

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8. Appendices

N/A

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9. Revision History

| Version Number | Amendments/ Reasons for change |
|----------------|--------------------------------|
| 01 | Initial Release |
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