FRIABILITY (GRANULES AND SPHEROIDS)

INTRODUCTION

In many cases, such as with hard coated and uncoated tablets, granules and spheroids, it is impossible to determine the friability of the dosage form using a conventional tablet friability tester (based on the Roche friability drum) even if the test time is extended, simply because the resistance is such that no measurable attrition is obtained. The energy imparted by the friability tester is just not sufficient to generate quantifiable changes in surface mass.

The **Friabimat SA-400** is a new instrument specifically designed to address this particular problem by offering a method of friability measurement suitable for the hardest and most robust of solid dosage forms.

DESIGN AND CONSTRUCTION

The Friabimat was originally designed as a method to effectively determine (under precisely defined, controlled and reproducible conditions) the friability of hard pellets and granules prior to further processing, for example, drum coating.

The instrument is particularly useful in detecting variations in mechanical properties between different formulations and batches and is a convenient tool in both research and development and quality control applications.

Following review, the instrument has now been included in the 7th edition of the European Pharmacopoeia under **Chapter No. 2.9.41 Friability of Granules and Spheroids.**

This describes the Friabimat under Method B Oscillating Apparatus 2.9.41.-2.

The Friabimat's range of application has since been extended to include hard coated and uncoated tablets and other dosage forms which fall outside the scope of the standard friability tester.

For the purpose of the test, the sample to be tested is confined within a standard 105 mL glass bottle (measuring approx. 85 mm high x 49 mm i.d. with twist-off cap) which serves as the sample container.

During operation, this sample container is secured by means of a spring clip to the sample container holder horizontally mounted on the end of an oscillating arm having an arc of 37 degrees at a radius of 152 mm from the centre of oscillation.

The abrasive action is generated by the horizontal shaking movement of the oscillating arm which causes the samples to rub against and collide with each other and/or the internal surfaces of the sample container.

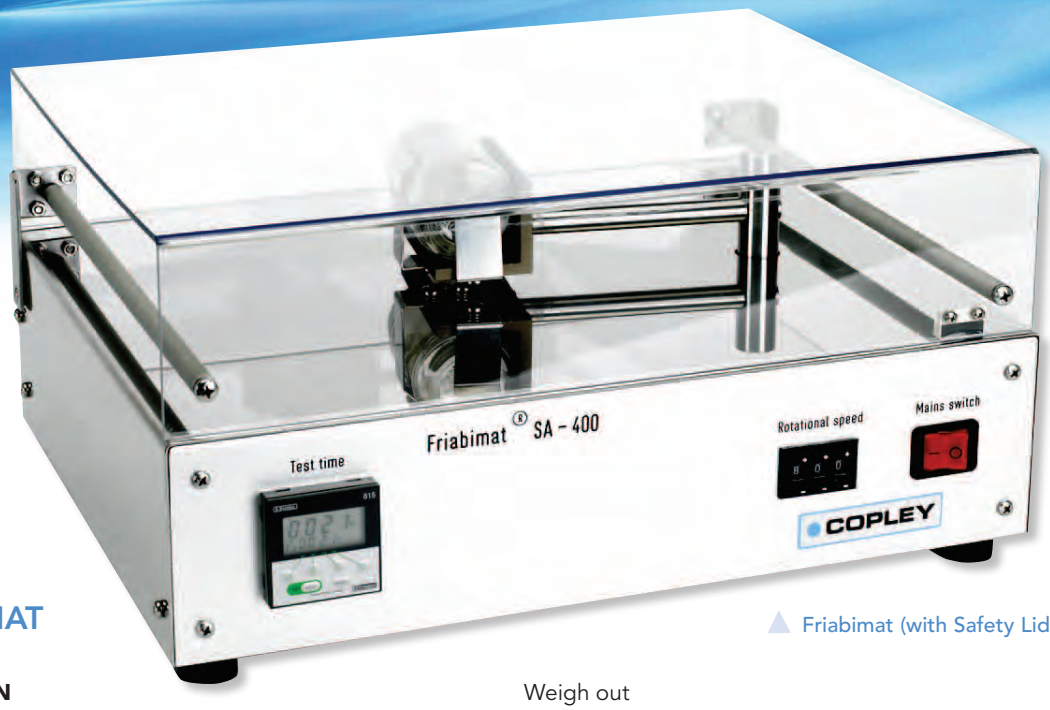
The intensity of the abrasive action and the duration of the test can be adjusted via the controls mounted on the front panel between 0 and 400 oscillations per minute and 0 and 9999 seconds respectively.

This enables the user to optimise the test conditions applicable to each formulation and reproduce it at will.

Average test times are between 2 and 4 minutes. The combination of these short test run times, together with the use of inexpensive, commercially available glass bottles as the sample container, means that it is possible to carry out tests economically in batches, as opposed to singularly on an infrequent basis.

The Friabimat measures 440 x 300 x 220 mm (w x d x h) and weighs 13 kg.

Friabimat (with Safety Lid Open)



Friabimat (with Safety Lid Closed)

FRIABIMAT

OPERATION

Adjust the number of oscillations to the desired frequency by adjusting the thumb wheel switches on the rotary speed adjuster mounted on the front panel to the appropriate setting (between 0 and 400 oscillations per minute).

Now set the test duration using the push button timer (between 0 and 9999 seconds).

Note: Shake for about 240 seconds at approx. 400 oscillations per minute for hard dosage forms, or, for example, 120 seconds at 140 oscillations per minute for soft dose forms. Optimise these settings according to the dosage form concerned.

The Friabimat is now ready for operation.

Take a sample of the formulation to be tested and remove any fine particles present in the sample using a 355 micron sieve.

Weigh out approx. 10 grams (m1) of the product into a sample container ensuring that the twist-off cap is well secured. Now place the sample container into the spring clip fastening on the Friabimat provided, to secure it and close the safety lid.

Start the test by pressing the appropriate key on the timer. The unit will switch off automatically on expiration of the preset time. The time remaining to the end of the test is displayed on the timer during operation.

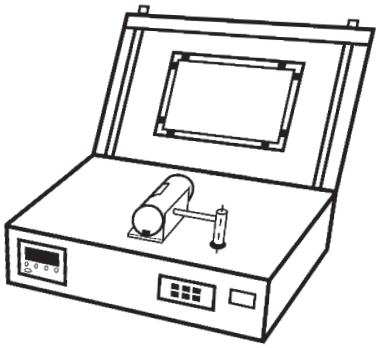
Note: The Friabimat is fitted with a **safety interlock** which automatically pauses operation if the safety cover is opened during a test. The test can be re-started once again by simply closing the lid.

At the end of the test, sieve as at the start of the test and re-weigh (m2). Perform three tests and calculate the mean value.

Express the results in terms of % weight loss using the formula (m1-m2) x 100 divided by m1.

KEY FEATURES

- Quantifiable friability of hard tablets, granules and pellets
- Horizontal shaking action
- Programmable shaking rate (0-400 oscillations per minute)
- Programmable test times (0-9999 seconds)
- Stainless steel case for production environments
- Clear acrylic lid with magnetic interlock for safe operation
- Interchangeable glass sample containers for rapid throughput
- Oscillation frequency verification certificate (optional)



Oscillating Container

Cat. No.	Description
1450	Friabimat Model SA-400 including 1 Glass Container
1451	Oscillation Frequency Verification Chart
1452	Pack of 100 Spare Glass Containers