

Friability

INTRODUCTION ▶▶▶

Copley Philosophy			
Robust	✓	Reliable	✓
Easy to use	✓	Compliant	✓

Friability is the tendency for a tablet to chip, crumble or break following compression. This tendency is normally confined to uncoated tablets and surfaces during handling or subsequent storage.

It can be caused by a number of factors including poor tablet design (too sharp edges), low moisture content, insufficient binder, etc.

For obvious reasons, tablets need to be hard enough such that they do not break up in the bottle but friable enough that they disintegrate in the gastrointestinal tract.

The basic apparatus comprises a drum and a motor capable of rotating the drum at 25 rpm. The standard friability drum has an inside diameter of 287 mm and a depth of 38 mm and is fitted with a curved baffle which subjects the tablets to be tested to a drop of 156 mm.

The sample (normally 10 tablets) to be tested is first weighed and then placed into the drum. The drum is then rotated 100 times, any loose dust from the sample removed and the sample re-weighed.

The friability of the sample is given in terms of % weight loss (loss in weight expressed as a percentage of the original sample weight). A maximum weight loss of not more than 1% is considered acceptable for most tablets.

Abrasion drums for carrying out tests into the attrition of tablets caused by the product rubbing together during transit are also available on request.

In some cases, such as coated tablets, granules and spheroids, it is not possible to determine the friability of the product using a conventional friability tester since the dosage form is simply too hard for meaningful weight losses to be generated.

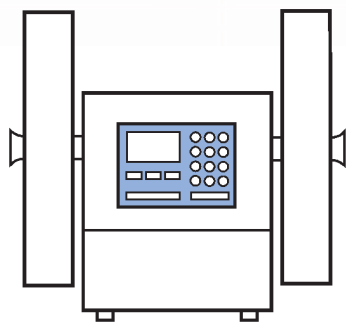
The Friabimat described on Pages 45 and 46 is a new instrument that has been specifically designed to address this problem: it operates by oscillating the sample container at high frequencies causing the sample contents to collide with each other and/or the internal surfaces of the container.

All Copley Friability Testers feature:

- Simple, easy-to-use operation; ensures that the number of operations required to perform a test is kept to a minimum
- Full supporting documentation (including full IQ/OQ/PQ qualification documentation where applicable)



FRIABILITY TESTER SERIES FR



Based on an original design by Roche, the friability tester has now become an accepted standard throughout the pharmaceutical industry for determining the resistance of uncoated tablets to the abrasion and shock experienced in manufacturing, packing and shipping operations.

Such stresses can lead to capping, chipping, abrasion or even breakage of the tablets.

Whilst the basic design remains unchanged, considerable advances have been made in terms of reliability and ease of use which have now been incorporated into current units.

PHARMACOPOEIAL COMPLIANCE AND VALIDATION

In order to meet your individual requirements, Copley provide a three tier approach to regulatory compliance and validation:

- **Certificate of Compliance to USP/ Ph.Eur.:** Included with each unit. Written statement that the product, by design, complies with the current pharmacopoeial specifications.
- **Laser Numbering and Certification:** Identification and measurement of critical components (i.e. the friability drum) to provide **documented verification** of compliance with pharmacopoeial requirements. Available as an optional service.
- **IQ/OQ/PQ Qualification Documentation:** Comprehensive documentation to guide the user through the installation, operating and performance checks of the equipment, in its operating environment, using specified test protocols. It provides a comprehensive record of the suitability of the equipment to perform its specified task, to be created and archived. Available as an optional service.

Please see the ordering information for further details on our verification and IQ/OQ/PQ services.

DESIGN AND CONSTRUCTION

Designed in accordance with the specifications as laid down in **Eur. Ph. Chapter 2.9.7** and **USP Chapter <1216>**, the FR Series forms the basis of our range of friability testers for **uncoated tablets**.

The standard FR Series operates at a **constant speed of 25 rpm +/- 1**.

It is available in two variants, that is to say, with either one (Model FR 1000) or two test drums (Model FR 2000).

Similar in construction to the fixed speed FR Series, the **Friability Series FRV** differs only in having **variable speed between 20 and 60 rpm**.

The speed is controlled via the membrane keypad in steps of 1 rpm. The variable speed allows the operator to subject the tablets under test to varying stresses and therefore determine an optimum for each type.

As on the FR Series, the duration of the test can be selected in either revolutions of the drum (1 - 999,999) or time (up to 99 hours, 59 minutes, 59 seconds).

During the test run, the nominal test duration and remaining test duration, in either revolutions or time, is indicated on the LCD screen, together with the selected speed.

The control of all models is provided by a membrane keypad linked to a 4-line 20 character back-lit LCD screen.



◀ Friability Tester FR 1000
(for Uncoated Tablets)

FRIABILITY (UNCOATED TABLETS)

DRUMS

The friability drum has been designed for testing the rolling and impact durability of tablets and has a single curved baffle which allows the tablets to be tested to rise and then drop through a distance of approx. 156 mm. Premature fracture or sign of wear at the edges indicates that such tablets may not withstand the rigours of transportation.

All friability drums are now fitted with an aperture such that **it is no longer necessary to remove and open the friability drum in order to load and remove the samples.** At the start of the test, the drum automatically revolves until the aperture(s) faces the operator so that the tablets can be loaded. On completion of the test, the drum stops and then reverses automatically emptying the contents of the drum into the waiting collection tray(s). All friability drums are completely **interchangeable**, i.e. they will fit either side of the tester.

Abrasion drums for carrying out tests into attrition are also available as an optional extra. The Abrasion drum comprises of a drum 20 cm diameter with a series of baffles which carry the tablets to a predetermined height before sliding off and reproduces the action of the tablets rubbing against each other during transport.

All testers can be equipped with a choice of either USP friability drums and/or abrasion test drums. Dual drum units can for example be fitted with one friability and one abrasion drum thus allowing comparisons to be made between the two parameters under identical test conditions.

Friability Tester
FR 2000 with
1 Friability Drum
& 1 Abrasion Drum ►



OPERATION

Considerable attention was paid to the design of the FR and FRV series to ensure that the number of actions necessary to perform a test are kept to a minimum. Consequently, once the method (number of revolutions or time) has been selected and the test duration set, it is only necessary to press the START key to initiate the test.

The standard test procedure is to take a sample of 10 tablets (a sample equivalent to 6.5 grams should be taken if the tablets weigh less than 650 mg), the weight of which has already been determined (W1). The tablets should be de-dusted prior to weighing.

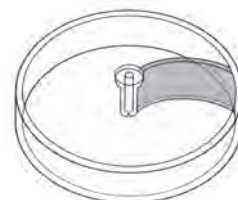
The tablets are then placed into the test drum and allowed to rotate 100 times. The tablets are then re-weighed (W2) having first removed any accumulated dust and the results calculated in terms of % weight loss utilising the formula $(W1-W2) \times 100$ divided by W1. In general, a maximum

weight loss of not more than 1% is acceptable for most tablets. If necessary, repeat the test twice more basing the result on the mean of the three tests.

Dimensions (mm):

FR 1000 / FRV 1000 =
290 x 360 x 350 mm (w x d x h)

FR 2000 / FRV 2000 =
342 x 360 x 350 mm (w x d x h)



Schematic of Friability Drum



Schematic of Abrasion Drum

Cat. No. Description

1401	Friability Tester FR 1000 (Fixed Speed - 1 Drum)
1402	Friability Tester FR 2000 (Fixed Speed - 2 Drums)
1403	Friability Tester FRV 1000 (Variable Speed - 1 Drum)
1404	Friability Tester FRV 2000 (Variable Speed - 2 Drums)
1405	Extra for Numbering & Certification (per Drum)
1406	IQ/OQ/PQ Documentation Pack
1407	Abrasion Drum (Optional extra)
1408	Friability Drum (Spare)
1409	Device for angling friability tester at 10 degrees
1410	Qualification Tools (Certified Stopwatch, Tachometer and Rule)