

Friability

Background: Friability Testing

Friability is the tendency for a tablet to chip, crumble or break following compression and can occur due to shock or abrasion during subsequent manufacturing steps, packaging or shipping. Normally limited to uncoated tablets and surfaces, it is a tendency that can significantly erode tablet quality.

Tablets need to be hard enough so that they do not break up in the bottle, to safeguard product stability and dose uniformity, but sufficiently friable to disintegrate in the gastrointestinal tract and release the active(s).

Chapters Ph. Eur. 2.9.7 and USP <1216> describe reproducible and standardised methods and equipment to determine the friability of a tablet.

Friability

Test Apparatus & Method

A standard friability drum has an inside diameter of 287 mm and a depth of 38 mm. Each drum is fitted with a curved baffle which subjects tablets to a drop of 156 mm during rotation.

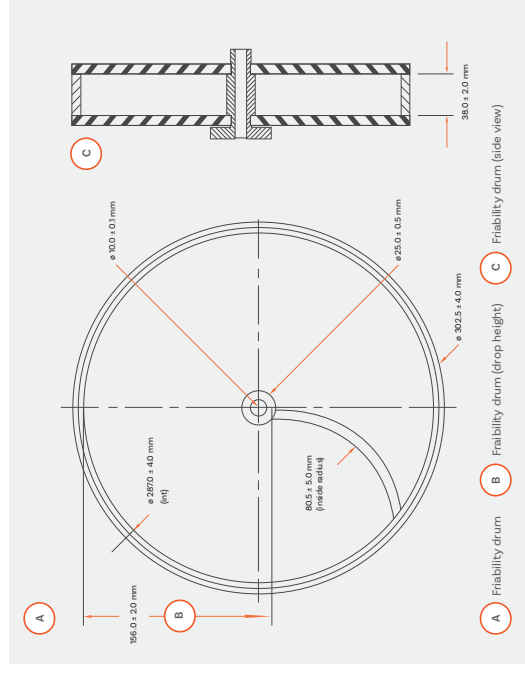
The sample (normally 10 tablets) to be tested is first weighed and then placed into the drum. The drum is then rotated 100 times at a speed of 25 rpm. Any loose dust from the sample is removed and the sample re-weighed.

Friability of a sample is defined in terms of percentage (%) weight loss (loss in weight expressed as a % of the original sample weight). A maximum weight loss of no more than 1% is considered acceptable for most tablets.

Attrition caused by tablets rubbing together can also be measured using this method with a special abrasion drum.

For coated tablets, granules and spheroids, friability cannot be determined using a conventional friability tester, as the dosage form is too hard for meaningful weight loss measurements. Alternative equipment that oscillates the sample at high frequencies is available for this purpose (see Ph. Eur. 2.9.41).

The abrasive forces generated by the horizontal shaking movement of the oscillating arm of this equipment allows users to easily optimise test conditions for each type of formulation with simple-to-use programmable controls.



A

B

C

A

B

C

Friability: FRVi Series

Advanced friability testers for all tablet types

Providing highly reproducible and cost-efficient friability testing, the FRVi series of friability testers from Copley allow analysts to easily characterise the critical tendency of tablets to chip, crumble or break.

Based on an original design by Roche, the Copley FRVi Series friability tester is an established standard within the pharmaceutical industry. Equipped with advanced design features, ranging from convenient sample loading and unloading to an integrated friability calculator, the FRVi Series streamlines the workflow associated with routine friability testing.



Ph. Eur. and USP compliant



Extensive data output options



Intuitive touchscreen control to simplify operation



Convenient drum emptying function



Integrated calculation of % tablet weight loss



Built-in 10° angling device for larger tablets



FRVi Series: Key Features



Intuitive touchscreen control with icon-based menu structure simplifies operation and clearly displays test parameters throughout run



Robust metal case with advanced corrosion protective coating



Small unit footprint saves previous benchtop space



Compatible with friability and/or abrasion drum(s)

FRVi Series: Touchscreen User Interface



- A Setting a test parameter
- B Set v Actual test parameters (before test run)
- C Set v Actual test parameters (during test run, with test progress bar)
- D Settings menu
- E Friability calculation screen
- F Report output settings menu
- G Motor speed (RPM) verification

Reporting

Extensive data output options are available as standard, including direct reporting to a printer or PC.

Reported parameters

- Speed (revolutions per minute)
 - Set
 - Average
 - Maximum
 - Minimum
- Number of revolutions
 - Set
 - Actual
- Friability calculations
 - Start weight (g)
 - End weight (g)
 - Friability (%)



Compliance & Maintenance



- ✓ Certificate of compliance to Ph. Eur./USP provided as standard
- ✓ Comprehensive IQ/OQ/PQ documentation packages and toolkits available



Built-in 10° switching leg for testing larger tablet and capsule types

Key Features:

- Intuitive menu structure enables users to locate features quickly and easily
- Easy-set user-configurable test parameters: Speed (revolutions per minute), Total revolutions, Test duration (HH:MM:SS)
- Status of 'Actual' v 'Set' test parameters clearly displayed throughout testing
- Test progress bar provides clear and constant indication on run status
- Resistive touchscreen interface can be operated with gloves on
- Hygienic wipe-clean screen
- High productivity - easy system set-up and operation minimises training burden
- Calculation of Friability Ratio

Choose your Friability System



FRV 100i

Cat Number
1431



FRV 200i

Cat Number
1432



Friabimat SA-400

Cat Number
1450

Pharmacopoeial Compliance
Ph. Eur. 2.9.7 USP <1216>

Tablet Types
Uncoated tablets

Test Station Capacity
1 drum

Unit Dimensions (w x d x h)
316 x 343 x 325 mm

Pharmacopoeial Compliance
Ph. Eur. 2.9.7 USP <1216>

Tablet Types
Uncoated tablets

Test Station Capacity
Up to 2 drums

Unit Dimensions (w x d x h)
407 x 343 x 325 mm

Pharmacopoeial Compliance
Ph. Eur. 2.9.41-2 (Method B)

Tablet Types
Hard tablets, Granules

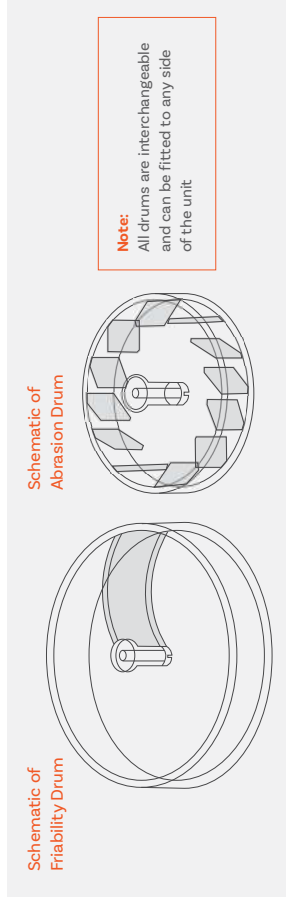
Test Station Capacity
1 oscillating container

Unit Dimensions (w x d x h)
440 x 300 x 220 mm

FRVi Series: Friability & Abrasion Drums

Fitted with an aperture for convenient sample loading and unloading, the FRVi Series drums automatically revolve to face the operator for easy sample loading. Upon test completion, simply tapping the 'empty drum' icon on the touchscreen empties the drum contents into the waiting collection tray(s), ready for weighing.

With a choice of either USP Friability and/or Abrasion drums, the versatile FRVi Series allows direct comparisons between the two parameters under identical test conditions.



FRVi Series: Technical Specifications

Pharmacopoeial Compliance

Ph. Eur. 2.9.7
USP <1216>

User Interface

Resistive touchscreen

Test Duration Parameters

Time or Revolutions of the Drum(s)

Drum Rotational Speed Range

10 - 60 rpm (± 1 rpm)

Rotational Limit

Up to 60,000 rotations

Test Run Time

Up to 99 hours, 59 minutes, 59 seconds

Data Output

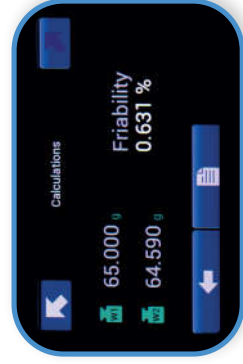
RS 232
USB A (for connection with a USB printer)
USB B (for connection with a PC)

Alarm

End of testing (audible)

FRVi Series & Accessories

Cat. No.	Description	Cat. No.	Description
1431	Friability Tester FRV 100i (Variable Speed - 1 Drum)	1405	Extra for Numbering & Certification (per drum)
1432	Friability Tester FRV 200i (Variable Speed - 2 Drums)	1406	IQ/OQ/PQ Documentation Pack
1407	Abrasion Drum (Optional extra)	1410	Qualification Tools
1408	Friability Drum (Spare)	1412	Re-calibration of Qualification Tools



FRVi Series: Friability Calculator

The integrated friability calculator removes the need for manual tablet weight loss calculations, reducing the risk of analyst calculation error and improving data accuracy.

Simply inputting start and end weight allows for automatic calculation of percentage (%) friability.

Friability results together with the test report are easily output to PC and printer.

Friability: Friabimat SA-400

For the hardest and most robust solid dosage forms which fall outside the scope of the conventional friability tester a higher-energy input instrument is needed to generate quantifiable changes in surface mass. The Friabimat, as described in Ph. Eur. 2.9.41, has been designed to generate the necessary abrasive forces required to define the friability characteristics of these types of dosage forms.

Not only useful for determining the friability of hard pellets and granules, the Friabimat is suitable for detecting variations in mechanical properties between different formulations and batches, making it a convenient tool for both research and development and quality control applications.



Friabimat SA-400: Key Features



Quantifiable abrasion of hard tablets, granules and pellets



Stainless steel case ideal for production environments



Clear acrylic lid with magnetic interlock to ensure safe operation



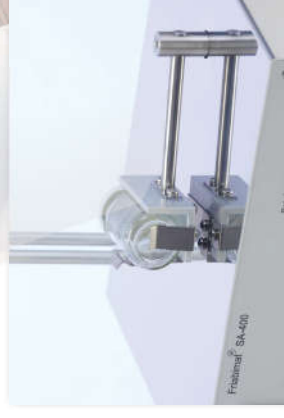
Option: Oscillation frequency verification certificate

Friabimat SA-400: Technical Specifications

Pharmacopoeial Compliance	Ph. Eur. 2.9.41:2 (Method B)
Shaking rate	0 - 400 oscillations per minute
Test Run Time	Up to 9,999 seconds
Test Station Capacity	1 Oscillating Container
Dimensions (w x d x h)	440 x 300 x 220 mm



Friabimat with safety lid open



Oscillating Container

Friabimat SA-400 Accessories

Cat. No.	Description
1450	Friabimat Model SA-400 including 1 Glass Container
1451	Oscillation Frequency Verification Chart
1452	Pack of 100 Spare Glass Containers
1453	IQ/OQ/PQ Documentation Pack
1455	Qualification Tools
1456	Re-Calibration of Qualification Tools
1454	355 Micron Sieve