
FRIABILITY TESTER SERIES FR & FRV



reliability and ease of usage which have now been incorporated into modern day units.

INTRODUCTION

The Friabilator has now become an accepted standard throughout the pharmaceutical industry for determining the resistance of 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



PHARMACOPOEIAL COMPLIANCE AND VALIDATION

In order to meet your individual requirements, Dr. Schleuniger Pharmatron provide a three tier approach to regulatory compliance and validation.

- Each Friability Tester is checked by our quality control department prior to despatch and supplied as standard with a **Certificate of Compliance** documenting the test protocol used and certifying conformity with the appropriate Pharmacopoeia.
- In addition to this general Certificate of Compliance, some of you have asked us for specific certification on certain critical components, for example, the Friability Drum. If you require this additional service, please refer to the appropriate ordering information on **Numbering and Certification**. This service includes the numbering of the individual component concerned and the provision of a detailed certificate indicating the actual measurements relating to that component and the metrology equipment (and its traceability) used in measuring them.
- Finally, if you require help in the validation process, then request our **IQ/OQ Documentation** which provides the necessary SOPs (Standard Operating Procedures) to guide you through the installation and operation qualification process. If you prefer, we or our official agent can often undertake this work for you. Please consult our technical staff for further details.

DESIGN AND CONSTRUCTION

Designed in accordance with the specifications as laid down in **USP** and other Pharmacopoeia, the FR Series forms the basis of our range of Friability Testers.

Friabilator

Product Information

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, 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 remaining test duration in either revolutions or time (or if you prefer revolutions or time remaining to the end of the test) 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.

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 transport.

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.

OPERATION

Considerable attention was given in the design of the 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, 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 0.8 to 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 mm (W) x 360 mm (D) x 350 mm (H)

FR 2000 / FRV 2000 = 360 mm (W) x 360 mm (D) x 350 mm (H)