PTF 110, PTF 210, PTF 310 and PTF 610

Tablet Friability Test Instruments

The PTF series of tablet friability and abrasion test instruments is manufactured in compliance with the USP <1216>, EP <2.9.7> and JP <14> Pharmacopoeias. The instruments are available with one, two, three or six drums. They feature an automated sample discharge at the end of a test and an interface to connect an analytical balance.

One of the testing criteria for mechanical strength of tablets and cores according to the USP <1216>, EP <2.9.7>, JP <14> and other pharmacopoeia is friability and abrasion testing. During the process of coating, transportation and packing the tablet will lose some amount of weight. To measure this weight loss, the samples are counted and weighed. Then the friability test is performed following the individual monographs of the relevant Pharmacopoeia. The tablets are tumbled at each turn of the drum of the friability testing instrument by a curved baffle that extends from the middle of the drum to the outer wall.

Friability Test Start

Clean the samples from any dust prior to the test. Weigh the samples and introduce them into the drum of the instrument. The drum can easily be opened for loading and cleaning. Alternatively, it is possible to use the discharge opening to load the samples without opening the drum first. Select a test method and start the run. The LCD with color-changing backlight shows the test status and results. Once the test is finished the drum revolution stops and the samples are automatically discharged into a collector.

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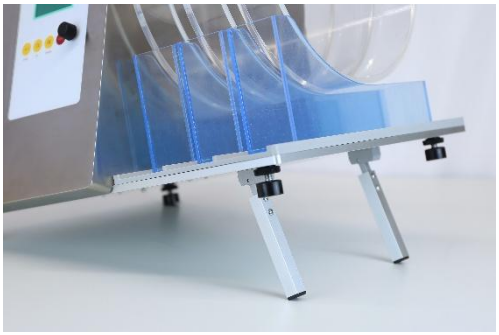
The collector is made from clear Plexiglas and is fixed to the instrument base plate by magnets. It can easily be removed for cleaning. The samples then must be inspected for broken tablets, de-dusted and weighed again. The weight difference before and after the test is determined as friability; this usually should not exceed 1%. It is possible to connect a balance to the instrument to include the weight before and after the test as well as the weight loss on the result report.



Optional 10° Angle Stand

Tablets of a weight >650mg, with a bigger diameter or odd shaped samples must be tested while the instrument is raised to an angle of 10° on one side using collapsible feet.

Optional Abrasion Drums

The standard supply scope includes the friability (also known as “Roche”) drum, but an abrasion drum is available as an option. The standard friability drum causes the samples to roll and fall during the test while the abrasion drum continuously puts the sample under stress by contact with lamellas.

Optional Friability Drums with Anti-Static Coating

Friability drums are available with an additional anti-static coating as an option. This makes cleaning of the drum after the test significantly easier.

Friability Drum Design

The friability drum is made from Plexiglas and is separated into two parts: the drum body and a removable cover. The cover is opened to fill the drum and to clean from the inside when required. The drum has an opening through which the samples are discarded at the end of a test by reversing the rotation direction. The opening may also be used to fill the drum without removing the cover. Every friability drum is delivered including a certificate of conformity to the valid USP and EP Pharmacopeia.

Drum Rotation Speed

The PTF instrument rotates the drums at a speed of 15 to 100 rpm. Typically, the test is performed at a rotation speed of 25 rpm. The instrument can be set up to work with one fixed speed setting, i.e. 25 rpm or to allow setting the speed for each test or method. In the method you can set either the number of drum rotations or a testing time.

Available Models

PTF 110 and PTF 210 friability testing instruments with 1 and 2 drums

PTF 310 and PTF 610 friability testing instruments with 3 and 6 drums

Instrument Design

The instrument is made from high quality stainless steel which fully meets GLP requirements.

User Interface

The PTF instrument is operated by using a click wheel to navigate menus on the LCD screen and by functional keys to shortcut frequent operations. The display is backlit in changing colors that show the instrument status in a familiar traffic light system (green, yellow, red). Navigating the menu is quick and simple. The color-changing display makes it easy for the user to see when his input is required to proceed.

The instrument has a method and a user management system. Methods can be programmed, edited and stored directly on the instrument. Users can be created and assigned different user levels according to their roles (method or standard user, only one Admin).

Access to the instrument is protected by a login with username and password. Optionally a quick test menu can be accessed without logging in to the instrument first. This way tests can be performed with the instrument in case user access control and testing according to defined methods is not required.

Integrated Report Printer

The PTF instrument features an integrated report printer to document the test and calibration results. An integrated printer saves valuable bench space in your laboratory. The detailed result report includes an automatic weight loss calculation.

Data Storage and Export

A USB flash drive can be connected to the instrument to save and load methods in .csv-format. Printouts can be stored as text files. Results can be transmitted to external systems such as LIMS via a serial interface. Furthermore, instrument firmware updates can be installed, and factory settings be restored by using the flash drive without the need for any PC or programming tool.

Calibration

The PTF instrument features dedicated calibration programs. The user is guided through each step of the calibration and a report is printed automatically.

The reports are saved on the instrument and can be printed later as well. A programmable qualification interval timer reminds the user to perform the instrument calibration once it is due. Each time the instrument is turned on it performs a quick self-check to ensure it is ready for operation. The result of the self-check can be documented via the integrated printer as well.

Example Test Report

```
TEST REPORT - RUN TEST

Department:         Department
Device-ID:          ABC123
Device:             PTF 110
SN:                 35249
Version:            2.11
Date:               2025-08-05
Time:               13:37:20
User:               Admin

Method:             method1
Product:            product1
Batch:              ABC123
Analysis-ID:        22
Speed:              25 rpm
Revolutions:        4
Time:               10 s
Limit:              1.0000 %
Drum Type:          friability
10° Stand:          yes
Samples:            10
Total Runs:          1

Results:

.....Run: 1.............
Start weight:       145.0000 g
End weight:         144.0000 g
Weight Incr.:       1.0000 g
Weight Incr.:       0.6897 %
.....................................

Test Result:

Test passed

Printed: 2025-05-08  13:41:06

Operator name


Signature
```

Customer department
Customer device-ID
Instrument model name
Instrument serial number
Instrument firmware version
Date of test start
Time of test start
User performing test
Method name
Product name
Batch number for each test
Analysis ID (automatically ascending)
Set drum rotation speed
Set number of drum revolutions
Total runtime
Limit for weight loss to pass test
Type of drum to be used
10° angle stand to be used
Number of samples to be tested
Total runs

Received results
Start weight (measuring weight is optional)
End weight
Absolute weight increase
Relative weight increase

Test has passed

Date and time when the report was printed

Space to write operator name

Space to sign the report

PT-Node Network Adapter for Printing and Data Transfer

PT-Node is an adapter that connects up to two Pharma Test instrument simultaneously to a network using a wired LAN connection. This way you can print test results from the instrument via your web browser on any local or network printer. Furthermore, it is possible to transfer the test results from the instruments to external systems in the same network. PT-Node supports these PTF instruments.

Advantages

» Drums are easy to open for loading and cleaning, alternatively use discharge opening for loading
» Graphical LCD screen showing actual and target settings
» Integrated protocol printer reduces bench space requirements
» Detailed result report including weight loss calculation and evaluation of the results
» Automated sample discharge at the end of a test run
» Dual operation mode: number of revolutions or rotation time
» Variable drum rotation speed or locked speed mode
» Determine the sample weight by balance to automatically calculate weight loss
» Programmable qualification interval timer reminds the user to perform instrument calibration
» Dedicated calibration programs and reports
» Copy methods between instruments by using a common USB flash drive
» Export test reports as text files
» IQ/OQ documents included free of charge

Features

» Fully USP <1216>, EP <2.9.7> and JP <14> compliant
» Determine friability and abrasion (optional) of uncoated tablets
» Programmable for number of drum revolutions or rotating time
» User management system
» Method management system
» Connect a balance to determine the sample weight (optional, weight can be entered manually)
» Integrated calibration programs
» Connect USB flash drive to copy methods and store test reports
» Integrated protocol printer

Standard Scope of Supply

PTF x10 comes ready to use with the following standard scope of supply:

» One, two, three or six standard friability drum(s) made from Plexiglas, in compliance with the USP, EP and DAB pharmacopoeia
» Comprehensive documentation included (PDF, hardcopies optional):
  › User manual
  › DQ/QC instrument compliance test certificate
  › IQ documentation
  › OQ documentation
  › Instrument logbook

Options

In addition to the standard scope of supply Pharma Test offers a broad range of accessories and options including:

» Friability drum with anti-static coating (part no. 224-1110)
» Tablet abrasion drum with lamellas (part no. 224-1120)
» 10° stand to test large samples (PTF 110 & PTF 210: part no. 224-0505, PTF 310: 224-0535, PTF 610: 224-0565)
» PT-Node network adapter (part no. 24-00100)
» Alternative external ticket printer (part no. 29-02200)
» Full range of certified validation tools available

The waste containers are held by magnets and are easily removed for cleaning

Technical Specifications

Parameter	Specification
Number of test drums	PTF 110: 1, 1x right side PTF 210: 2, 1x right side, 1x left side PTF 310: 3, 3x right side PTF 610: 6: 3x right side, 3x left side
Drum rotation speed range	15 – 100rpm
Speed accuracy	±1 rpm
Number of rotations	Adjustable 2 – 9999, switchable to time mode
Testing time	Adjustable 2 - 9999 seconds, switchable to rotations mode
Method management	Up to 256 test descriptions (methods) can be stored on the instrument
User management	Up to 32 users with selectable user right levels can be stored on the instrument
Result data storage	Store copies of result reports by connecting a USB flash drive
Display	LCD with color-changing backlight
Data entry	Keypad with function keys and click wheel
Interfaces	USB type A host port to USB type B device port to connect flash drives, for serial data export and firmware updates RS-232 printer port for optional balance or external printer
Instrument housing	brushed stainless steel housing
Power	100-240 Volt, 50/60 Hz
Instrument Dimensions	PTF 110: approx. 39cm x 42cm x 42cm (width x depth x height) PTF 210: approx. 42cm x 42cm x 42cm (width x depth x height) PTF 310: approx.: 51cm x 42cm x 42cm (width x depth x height) PTF 610: approx.: 75cm x 42cm x 42cm (width x depth x height)
Packaging Dimensions	PTF 110: approx.: 60cm x 60cm x 79cm (width x depth x height) PTF 210: approx.: 60cm x 60cm x 79cm (width x depth x height) PTF 310: approx.: 60cm x 60cm x 79cm (width x depth x height) PTF 610: approx.: 80cm x 60cm x 74cm (width x depth x height)
Net /Gross Weight	PTF 110: approx.:16.5 / 26.5 kg PTF 210: approx.:18.0 / 28.0 kg PTF 310: approx.: 19.5 / 30.0 kg PTF 610: approx.: 28.0 / 52.0 kg
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

We reserve the right to make technical changes without any prior notice.