PTF 200

Double Drum Tablet Friability Test Instrument

PTF 200 is a double drum tablet friability and abrasion test instrument. It is manufactured in compliance to the USP <1216>, EP <2.9.7> and JP <14> Pharmacopoeias. The instrument features an automated sample discharge at the end of a test and the possibility 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

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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.

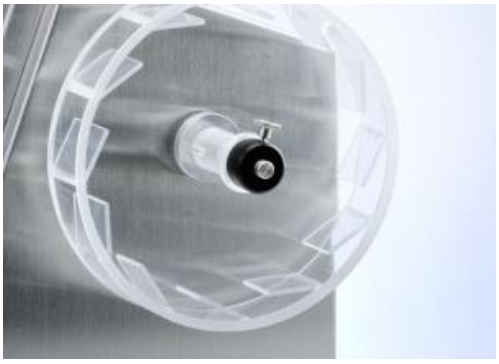
Clean the samples from any dust prior to the test. Weigh the samples and introduce them into any drum of the instrument. The drums can easily be opened for loading and cleaning. Alternatively it is possible to use the discharge opening to load the samples without opening the drum. Select a test method 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 discharged into collectors. The collectors are made from clear Plexiglas and are magnetically fixed to the instrument base plate. They can easily be removed for cleaning and secured back into the proper position. The samples then have to 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%.

Optional 10 Degree Angle Stand

Tablets of a weight >650mg or with a bigger diameter or odd shaped samples are 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”) drums, but abrasion drums are available as options. 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.



Different Speed Settings

A silent DC geared motor rotates the drums at a fixed speed of 25 rpm or at a selectable speed (setting can be locked). The actual drum is made from Plexiglas (Perspex) and is separated into two parts, the drum body and a removable cover, which opens to fill and clean the drum from the inside when required. The instrument itself is made from high quality stainless steel which fully meets the current GLP requirements. Friability drums with an additional anti-static coating are available as an option.

User Interface with Click Wheel Navigation

PTF 200 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 (administrator, operator, calibration technician).

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 (optional)

As an option PTF 200 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 the automatic weight loss calculation.

Storage Possibilities

A USB flash drive can be connected to the instrument to save and load methods in .csv-format. Print-outs can be stored as text files. 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

PTF 200 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 at a later time 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 optional integrated printer as well.

Advantages

» Drum is 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
» Connect a balance to determine the sample weight (optional, weight can be entered manually)
» Connect USB flash drive to copy methods and store test reports
» Integrated protocol printer (optional)
» User and method management system

Standard Scope of Supply

PTF 200 comes ready to use with the following standard scope of supply:

» Two friability drums made from Plexiglas (optional incl. anti-static coating), 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
  › Compliance certificates for vessels and stirring tools

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 right, 224-1115 left)
» Tablet abrasion drum with lamellas (part no. 224-1120 right, 224-1125 left)
» 10° stand to test large samples (part no. 224-0500)
» Internal thermo printer (part no. 224-2000)
» Certified calibration tools

Technical Specifications

Parameter	Specification
Number of Test Drums	2, 1 right side, 1 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
Keyboard	Keypad with function keys and click wheel
Interfaces	USB type A host port to USB type B device port to connect flash drives, for PC communication and firmware updates[1] LAN port for PC communication[1] RS-232 printer port for optional external printer[1] RS-232 balance port
Instrument Housing	Polished stainless steel housing with plastic frame
Power	110/230 Volt, 50/60 Hz
Instrument Dimensions	Approx. 50cm x 42cm x 47cm (width x depth x height)
Packaging Dimensions	Approx. 60cm x 60cm x 50cm (width x depth x height)
Net /Gross Weight	Approx. 18 / 23 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.

[1] PC communication and external printer support to be added in future firmware update