

PTZ 100 and PTZ 300

Single and Triple Station Tablet Disintegration Test Instrument

PTZ 100 is a single station tablet disintegration test instrument. PTZ 300 is the triple station version. Both instruments are manufactured in compliance to the USP <701/2040>, EP <2.9.1/2.9.2.1> and JP Pharmacopoeias. The instruments feature a method and user management system as well as an integrated report printer.



Tablet disintegration testing instruments are widely used in the pharmaceutical industry to evaluate the disintegration characteristics of formulations and the quality control of different dosage forms. All Pharma Test tablet and capsule disintegration testers are fully compliant with the current USP and EP Pharmacopeia and support both A-type and B-type baskets for regular or larger samples. They

feature a stainless-steel housing, to be more GMP compliant than painted housing designs. Often these instruments are used in QC and IPC laboratories where most of the other equipment uses stainless steel as well. This way the Pharma Test instruments certainly do not look out of place.



The disintegration basket which holds the glass tubes and discs, is placed into a metal holder and held by a magnet. The instrument detects if a basket is inserted or not. The illuminated LC-display shows status information, like the elapsed testing time. The disintegration basket is moved up and down by 55mm (each way) at a rate of 30 times per minute. At test start it is moved smoothly into the testing medium.

The instrument's heating system using a circulation pump warms the water inside the Plexiglas water bath up to the programmed target temperature, i.e. 37°C. A second sensor is used as a safety device which switches off the heater in case the temperature should rise outside the limit. A flow sensor, a thermal fuse and a thermal switch provide additional safety features to protect the system from overheating. The bath target temperature can be freely adjusted. Using the supplied temperature probe, the medium temperature can always be checked.

Depending on the operating procedure, the test is either automatically stopped if the pre-set time has expired or if the operator terminates the test once he saw that all samples have disintegrated. The basket then stops at its highest mechanical position. The standard "A"-type disintegration basket is supplied with six glass tubes and six plastic discs.



Optional „B“-Type Baskets

The three tube "B"-type basket according to EP <2.9.1.2> and USP <2040>, can be used to test larger samples. It comes ready to use with three glass tubes and three plastic discs and can easily be exchanged.

Other special baskets to test capsules or vaginal tablets are available as well.

User Interface with Click Wheel Navigation

PTZ 100 and PTZ 300 are 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 instruments have 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

PTZ 100 and PTZ 300 feature an integrated report printer to document the test and calibration results. An integrated printer saves valuable bench space in your laboratory.

Cleaning and Maintenance

For easy cleaning and maintenance, the Plexiglas water bath can be easily removed. Quick connect tube couplings connect the tubing to the heating system and automatically seal on both sides.

Date 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.



PT-Node Network Adapter for Printing and Data Transfer

PT-Node is an adapter that connects up to two Pharma Test instruments 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 PTZ 100 and PTZ 300.

Calibration

PTZ 100 and PTZ 300 feature dedicated calibration programs for temperature, basket movement and timer function. The result can be documented by a print-out. 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

- » Graphical LCD screen showing actual and target settings
- » Integrated protocol printer reduces bench space requirements
- » Result report includes disintegration time, actual temperature and number of persisting samples
- » Password protected access through user management system
- » 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
- » Transmit test result to external systems such as LIMS
- » IQ/OQ documents included free of charge

Features

- » Fully USP <701/2040>, EP <2.9.1/Test A and B> and JP compliant
- » Available as 1 and 3 station instrument (PTZ 100 and PTZ 300)
- » Determine disintegration time of tablets, capsules and other dosage forms
- » User management system
- » Method management system
- » Temperature probe to monitor medium temperatures
- » Integrated calibration programs
- » Connect USB flash drive to copy methods and store test reports
- » Integrated protocol printer
- » Self-sealing quick connect water bath connectors



Standard Scope of Supply

PTF 100 and PTF 300 come ready to use with the following standard scope of supply:

- » One “A”-type disintegration baskets for each testing station
- » One set of six glass tubes for each disintegration basket
- » One set of six disintegration disks for each disintegration basket
- » One flat bottom disintegration vessel for each testing station
- » One temperature probe
- » One bottle of ALGEX Magenta water preservative
- » 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:

- » “B”-type disintegration basket (part no. 107-2010)
- » Disintegration basket for gelatine capsules (part no. 107-2020)
- » Disintegration basket for vaginal tablets (part no. 107-2030)
- » PT-ODF basket for oro-dispersible samples (part no. 12-30000)
- » Auxiliary tube according to JP <2.09> for granules (part no. 101-2160-6)
- » Alternative external ticket printer (part no. 29-02200)
- » Certified calibration tools

Example Test Report

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TEST REPORT - RUN TEST

Department:          QC
Device-ID:           123ABC
Device:              PTZ300
SN:                  24926
Version:             2.7
Date:                2022-06-08
Time:                13:59:59
User:                ADMIN

Method:              method1
Product:             product1
Batch:               1234567890ABCDE
Analysis-ID:         7
Medium:              water
max.Time:            00:02:00
Nom.Temp:            37.0 °C
Basket:              A-type (6)
Volume:              800
Disk:                yes
Max. persisting:    2
Total Runs:          1

Results:

.....Run: 1.....
Act. Temp:           36.9 °C
End Time:            14:02:08
Dis. Time:           00:02:00
Persisting Samples: 0
.....

Test Result:

Test passed
Total Persisting Samples: 0

Printed: 2022-06-08 14:02:10

Operator name

Signature
    
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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)
 Medium used for test
 Maximum test time
 Nominal test temperature
 Basket type
 Volume (ml) in the test vessel
 Maximum number of samples to remain in basket
 Total number of test runs

Actual temperature
 End time of test
 Disintegration time
 Number of persisting samples after test end

Evaluation of the test result
 Test has passed
 Number of persisting samples after test end

Date and time when the report was printed

Space to write operator name

Space to sign the report

Technical Specifications

Parameter	Specification
Number of testing stations	PTZ 100: 1 basket; PTZ 300: 3 baskets
Stroke height	Fixed at 55mm
Stroke frequency	30 strokes / minute
Stroke accuracy	± 1 stroke
Temperature range	Adjustable from 25.0 to 45.0 °C
Temperature accuracy	± 0.3 °C
Safety systems	Pressure switch to detect liquid flow to protect from overheating; thermal switch and thermal fuse to protect the heating system in case of electrical fault
Testing time	Adjustable from 00:00:01 to 99:59:59 (hh:mm:ss)
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 external printer
Instrument housing	Polished stainless-steel housing with plastic frame
Power	230 Volt, 50/60 Hz or 115V, 50/60 Hz
Instrument dimensions	Approx. 42cm x 50cm x 47cm (width x depth x height)
Packaging dimensions	Approx. 60cm x 60cm x 50cm (width x depth x height)
Net /gross weight	Approx. 16 / 21 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.