

PTZ AUTO

Semi-Automated Tablet Disintegration Testing

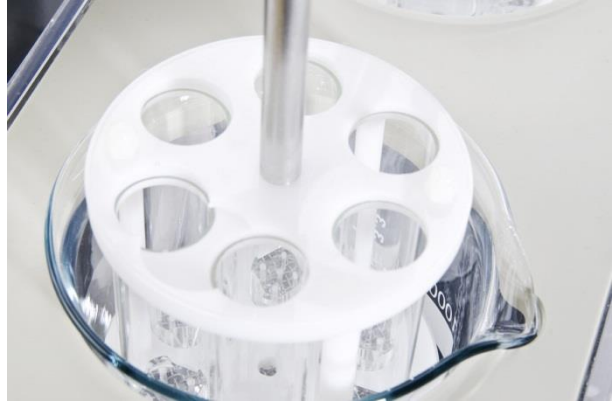
The PTZ AUTO disintegration test instruments are available as single, double, triple and four station systems. They are equipped in full compliance with the current USP <701/2040> and EP <2.9.1/2.9.2.1> Pharmacopoeia.



A large 320x240 pixel LCD screen and an alpha-numerical keyboard is used to edit product and test information, such as the disintegration time for each station, bath and media temperature. The total testing time for the station is displayed at the end of a run. Operator intervention to stop a run is also displayed. Print the individual disintegration time of each sample once it was visually detected by simply pressing the corresponding numeric key. All this information can be printed as a test report when a PCL printer is attached to the instruments parallel printer port.

Heating System and Mechanical Features

The built-in heating system uses a silent circulation pump and a heater to pre-heat the outer water bath over the range of 25.0-45.0° C. The actual bath temperature is always displayed and measured by an external manual temperature probe. The overheating protection secures automatic shut-down of the pump and heater in the event that no water flow is detected. A built-in safety system including an overheating detection sensor, a thermo switch and a thermo fuse closes down the heating when temperature exceeds +60°C or max. 95°C at the heater.



Cleaning and Maintenance



For easy cleaning and maintenance, the Plexiglas water bath can be easily removed. Fast Tube Couplings connect the tubing to the heating system. The digital controlled stroke mechanism is automatically adjusted to provide the USP / EP specified 30 strokes a minute to each station.

At the end of a test run, each basket is completely removed from the test media by the individual basket lift device. This feature is particularly useful if sustained released products are tested, which may require a medium change during the run.

Upgrade to Fully-Automated Instrument

The PTZ AUTO disintegration test instruments upgradeable to fully-automated instruments, which automatically determine independent disintegration data for each test sample using the PT-MKT electronic disintegration baskets. At the end of a test run, a test report can then be printed showing the minimum and maximum disintegration time, statistics as well as bath and media temperature, stroke frequency, and product data for each sample tube and each testing station.

PTZ32 Software

The PTZ AUTO is equipped with a serial RS-232 interface. The instrument can be connected to a PC and the PTZ32 software (21 CFR part 11 compliant) offers test methods, result filing, batch comparison and graphical information.

Advantages

Some of the highlights the PTZ AUTO instruments offer are:

- » Select from models with 1, 2, 3 or 4 stations to ideally meet your workload
- » Independent movement of all test stations
- » Automated lift to raise samples out of the medium at the end of a test
- » Automated time log when disintegration is observed
- » Integrated method management system
- » Excellent access to all vessels
- » DQ/QC, IQ and OQ documents included free of charge



Features

The main features of the PTZ AUTO instruments are:

- » Fully USP <701/2040> and EP <2.9.1/Test A and B> compliant
- » Available as 1, 2, 3 and 4 station instruments
- » GMP compliant stainless steel housing
- » Upgradeable to fully-automated operation
- » Store up to 16 methods with sample and test information

Standard Scope of Supply

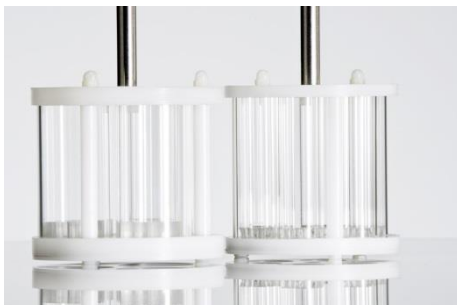
The PTZ AUTO instruments come ready to use with the following standard scope of supply:

- » One six position "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 1 liter glass beaker for each testing station
- » One bottle of ALGEX water preservative
- » Comprehensive documentation folder including:
 - > 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:

- » Alternative three position "B type" disintegration baskets for larger samples
- » Upgrade kit for fully-automated operation
- » DIN A4 PCL report printer



Example Test Report

```
-----
PTZ AUTO 2      S/N 024927 ** TESTREPORT **      TIME 13:23:24  DATE: 26.06.17
-----
                USER: ADMINISTRATOR                PRODUCT: SAMPLE
                BATCH NUMBER: 12345678910
                BATH TEMPERAT: 37.5°C                MEDIUM: WATER
                TARGET TEMP.: 37.0°C                MAX. TIME: 00:05:00
-----
BASKET 1
SAMPLE 1: DISINT.SINCE 0:04:51 (MAXIMUM)
SAMPLE 2: DISINT.SINCE 0:04:32
SAMPLE 3: DISINT.SINCE 0:04:19
SAMPLE 4: DISINT.SINCE 0:03:59 (MINIMUM)
SAMPLE 5: DISINT.SINCE 0:04:41
SAMPLE 6: DISINT.SINCE 0:04:34
-----
MEAN VAL. DISINT.TIME:      00:04:29
ABS. STANDARD DEVIATION:    00:00:16
REL. STANDARD DEVIATION:    5.0%
-----
Signature: _____
```

The test report shows the instrument type and serial number as well as current date and time in the first line of the report.

The second text block shows the name of the user who performed the test, the name of the product as specified in the method and the batch number entered for this test. Furthermore the bath temperature, target temperature and the name of the medium and the maximum testing time as specified in the method are printed.

The third text block shows the actual disintegration times for each position of the basket with the position number as in the first line of this text block. The shortest disintegration time is marked as minimum and the longest disintegration time is marked maximum.

The next text block contains statistical information for the disintegration time results. The first value is the mean value of the disintegration times above. The next value is the absolute standard deviation of these results and the last value the relative standard deviation as a percentage.

The last block can be used to sign the report.

Technical Data

Parameter	Specification
Display	LED backlit LCD, 320x240 pixels, 9" diagonal, approx. 90x120mm
Data Entry	Alpha-numerical keys and function keys
Testing Stations	1, 2, 3 or 4 stations – each independently operateable
Testing Time	Programmable from 1 second up to 23h, 59m, 59s
Auto Basket Lift	Raises samples out of the medium at test end
Security Systems	Password protection for calibration and validation
OQ Information	Programmable time sequence information to perform OQ
Thermostat	Built-in 1000 W heating tube and circulation pump, water bath temperature programmable from 25.0° - 45.0°C, overheating protection
Temperature Accuracy	± 0.3°C
Safety Systems	Pressure switch to protect from overheating (no liquid flow - no heating - no pump); Thermo switch and thermo fuse to protect the heating system in case of electrical fault
Stroke Frequency	30 per minute
Stroke Accuracy	± 1 stroke
Stroke Height	55 mm
Stroke Height Accuracy	± 1 mm
Interfaces	RS-232 serial interface for external control and data transfer Parallel PCL printer port (USB printer adapter available)
Instrument Dimensions (consider 10cm clearance in addition on each side)	PTZ AUTO 1 approx. 61 x 37 x 54cm (width x depth x height) PTZ AUTO 2 approx. 61 x 37 x 54cm (width x depth x height) PTZ AUTO 3 approx. 76 x 37 x 54cm (width x depth x height) PTZ AUTO 4 approx. 91 x 37 x 54cm (width x depth x height)
Packaging Dimensions	PTZ AUTO 1 approx. 80 x 51 x 70cm (width x depth x height) PTZ AUTO 2 approx. 80 x 51 x 70cm (width x depth x height) PTZ AUTO 3 approx. 80 x 51 x 70cm (width x depth x height) PTZ AUTO 4 approx. 107 x 77 x 95cm (width x depth x height)
Net / Gross Weight	PTZ AUTO 1 approx. 22 / 30kg PTZ AUTO 2 approx. 29 / 35kg PTZ AUTO 3 approx. 35 / 45kg PTZ AUTO 4 approx. 42 / 108kg
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.