PTZ AUTO EZ

Fully Automated Tablet Disintegration Testing

The fully automated PTZ AUTO EZ instruments are available as 1, 2, 3 or 4 station models. The instruments are capable to automatically detect the individual disintegration times of tablets and other solid dosage forms. Each automated disintegration basket can be operated independently. They are equipped in full compliance with the USP<701/2040> and EP<2.9.1/2.9.1.2> pharmacopoeia requirements.

A large 320x240 pixel LCD screen and an alpha-numerical keyboard are used to edit product and test information, such as the target disintegration time for each station and the bath and media temperatures. Up to 16 different testing methods can be filed in the instrument's memory.

The instruments are supplied with a complete PT-MKT electronic disintegration test basket for each testing position. Each basket is used to test six samples and includes six glass tubes and six disks. For larger samples of up to 30mm diameter we offer the PT-MKT33 basket ("B"-type according to USP <2040> and EP <2.9.1.2>). This basket is used to test three samples and is equipped with three tubes and disks only.
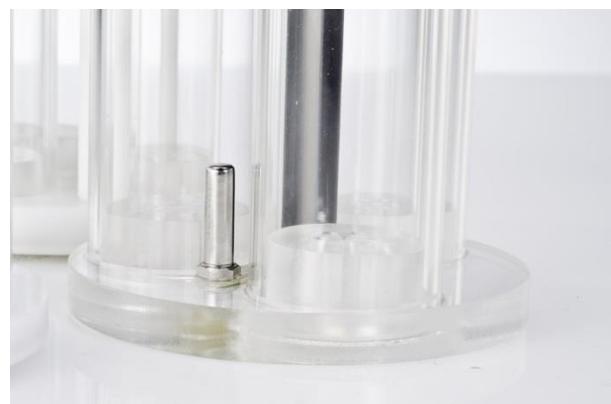
To enable the automated detection of the final disintegration time of each individual sample, the basket bottom sieves are split. A small metal ring is injected into the disks during manufacturing. This ring closes a contact between the two sieve halves once the sample has disintegrated. Each disk can be used in any of the testing positions. There is no need to place them always into the same tube or even basket. There is also no need to use different designs or tool to test different tablet shapes.

The complete basket design including sieve and disks are in compliance with the current USP and EP pharmacopoeias. The specific weight of the disks too is kept in full compliance.

The electronic disintegration baskets PT-MKT or PT-MKT33 are equipped with a temperature sensor to monitor the actual media temperature inside the glass beaker during operation. The disintegration time of each individual tablet within the basket is automatically detected. The total time is recorded and displayed. The printed report shows the individual disintegration time of each sample, minimum and maximum time, as well as mean value and standard deviation of all 6 or 3 samples.

The report includes the system information of bath and media temperature with no need of any external computer or software. Simply connect any suitable PCL printer to the parallel printer port of the PTZ AUTO EZ to receive your result report.

Heating System and Mechanical Features

The built-in heating system of the PTZ AUTO EZ instrument uses a silent circulation pump and a heater to pre-heat the outer water and keep the temperature within a tight tolerance. The actual bath temperature is displayed at all times and measured by an external movable temperature probe inside the water bath. The overheating protection system includes a pressure gauge to monitor the pump flow, a thermo switch and thermo fuse to cut the power supply in case of an electronical fault.

This secures automatic shutdown of the pump and heater in the event that no water flow is detected or the electronical control system fails. A built-in digital safety sensor placed at the end of the heating coil shuts down the heating when temperature exceeds +60° C max. 95°C at the heater.

Cleaning and Maintenance

For easy cleaning and maintenance, the Plexiglas water bath can be removed quickly. 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 lifting device. This feature is particularly useful if sustained released products are tested, which may require a medium change during the run.

PTZ32 Software

The PTZ AUTO EZ 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. Export functions to Excel and LIMS (Laboratory Information Management Systems) are available as options.

Advantages

Some of the highlights the PTZ AUTO EZ instruments offer are:

» Fully automated detection of individual disintegration end point times

» 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

» 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 EZ 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
» Equipped for 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 2EZ  S/N 024929 ** 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	Backlit LCD, 320x240 pixels
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 electronical 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 1EZ approx. 61 x 37 x 54cm (width x depth x height) PTZ AUTO 2EZ approx. 61 x 37 x 54cm (width x depth x height) PTZ AUTO 3EZ approx. 76 x 37 x 54cm (width x depth x height) PTZ AUTO 4EZ approx. 91 x 37 x 54cm (width x depth x height)
Packaging Dimensions	PTZ AUTO 1EZ approx. 80 x 51 x 70cm (width x depth x height) PTZ AUTO 2EZ approx. 80 x 51 x 70cm (width x depth x height) PTZ AUTO 3EZ approx. 80 x 51 x 70cm (width x depth x height) PTZ AUTO 4EZ approx. 107 x 77 x 95cm (width x depth x height)
Net / Gross Weight	PTZ AUTO 1EZ approx. 24 / 32kg PTZ AUTO 2EZ approx. 29 / 36kg PTZ AUTO 3EZ approx. 38 / 53kg PTZ AUTO 4EZ approx. 46 / 109kg
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.