Fully Automatic Disintegration Instrument: PTZ AUTO4 EZ

The fully automated **PTZ AUTO EZ** range is available directly in a 1, 2, 3 or 4 station configuration. The PTZ AUTO4 EZ Disintegration Test Instrument is equipped in full compliance with the USP<701/2040> and EP<2.9.1/2.9.1.2> pharmacopoeia requirements and ready to operate 4 automated disintegration baskets independently. 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 etc. A memory files up to 16 different testing methods.

The built-in heating system 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 always displayed 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 shut down 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.

For easy cleaning and maintenance, the Plexiglas water bath can be easily removed using the fast coupling system.

The stroke mechanism is automatically adjusted to provide the USP / EP specified strokes frequency and height for each one of the activated test stations.

At the end of a test run, each basket is completely removed out from the test media inside the glass beaker. This is most useful if sustained released products are tested, which may require a medium change during disintegration time testing.

The electronical 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. Each individual tablet within the basket is detected for disintegration time and 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. It 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 and receive your result report.

As the PTZ AUTO EZ is equipped with a serial RS-232 interface too, the connection to a Computer on which a suitable software is installed will always be possible. The PTZ32 software package (21CFR part 11 compliant) offers Test Method, Result filing, Batch Comparison and Graphical Information. Export functions to Excel and LIMS (Laboratory Information Management Systems) are available as option.

Operating Principle of the PT-MKT Auto Disintegration Baskets

The basket design as well as the sieve and disks are in compliance with the USP and EP pharmacopoeias. In order to enable an automated detection of the final disintegration of tablets and other solid dosage forms the bottom sieves are splitted. A small metal plate is attached into the Disks to give a contact when the tested sample has been disintegrated. Disk design and specific weight are kept in compliance to the mentioned pharmacopoeias. There is no need to place the disks always into the same tube or even basket, as there is no need to use different designs to be able to test various tablet forms.

For larger samples we offer the 30 mm basket (Test B - <2.9.1.2> EP and <2040> USP) PT-MKT33, this basket is equipped with three tubes and disks only.

PT-MKT Basket

Featuring

➢ alpha-numerical keyboard
➢ 320x240 Pixel large LC Display
➢ Test Information Filing up to 16 Methods

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- ➢ Individual start up for each station
- ➢ Media Temperature measuring in each vessel
- ➢ USP <701> and EP <2.9.1> compliant PT-MKT baskets
- ➢ USP <2040> and EP <2.9.1.2> PT-MKT33 baskets optional
- ➢ Print out of Run-Time Log at end of test
- ➢ Print out of Test Report incl. Statistics and Graphics
- ➢ OQ/PQ information system
- ➢ Manual Stop of Disintegration Times, press relevant key only, results are marked "M"
- ➢ Automated detection of the Disintegration Time of each Sample, results are marked "A"
- ➢ RS-232 interface, parallel Printer Interface - USB adapter option
- ➢ **ABS** Auto-Basket-Stop at highest position by built-in Basket Lift
- ➢ **TSC** system (Thermostat Safety Control system)
- ➢ Control by 21CFR part 11 compliant Software PTZ32, alternatively standard software package

Technical Data

Test Station:	4 independent operateable stations, holding each 1 PT-MKT or PT-MKT33 basket
Display:	LCD Display 320x240 Pixel
Keyboard:	alpha-numerical keyboard and function keys
OQ information:	programmable time sequence information to perform OQ test
Security:	password protected instrument calibration and validation procedures
Stroke Frequency:	30 strokes / minute
Accuracy:	± 1 stroke
Stroke Height:	55 mm
Accuracy:	± 1 mm
Basket Lift:	rises the baskets out of the media at end of test run
Thermostat:	built-in 1000 W heating tube and circulation pump Temperature adjustable within 25°- 45.0°C
Accuracy:	± 0.3°C
Safety System:	pressure switch to protect the heater from overheating (no flow - no heating - no pumping) thermo switch and thermo fuse to protect the heating system in case of an electronical fault
Memory:	up to 16 different test descriptive methods
Printout:	online printing of test report including individual disintegration times, statistics and graphics
Interface:	RS-232 port Parallel PCL Printer port USB adapter for both available as option

PT-MKT33 Basket

Options:

PTZ32 Standard Software, non CFR
PTZ32CFR Software single user or network version, 21 CFR part 11 compliant

PT-MKT33 electronic Basket for max. 30 mm Tablet Diameter in compliance with EP <2.9.1.2> and USP <2040>

Dimensions and Weights:

PTZ AUTO 4EZ

Net weight: approx. 27 kg
Gross weight: approx. 40 kg
Packaging: approx. 90 x 60 x 50 cm

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

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Typical Report Print (using a PCL LaserJet printer connected to the PTZ AUTO)

```
----------------------------------------------------------------------
                        **** TESTLOG ****
----------------------------------------------------------------------
PTZ AUTO 2 A S/N 010553                 TIME  9:14:56  DATE 18.04.02
----------------------------------------------------------------------
     USER: ORT                       PRODUCT: PLACEBO
                               BATCH NUMBER: 1234
                                     MEDIUM: WASSER
    TARG. TEMP.: 37.0°C       BATH TEMPERATURE: 37.1°C
----------------------------------------------------------------------
BASKET 1  S/N 010309, BASKET TEMP.: 36.8°C, (OPERATES SINCE  0:00:00)




----------------------------------------------------------------------
----------------------------------------------------------------------
                     ***** TEST REPORT *****
----------------------------------------------------------------------
PTZ AUTO 2 A S/N 010553                 TIME  9:15:45  DATE 18.04.02
----------------------------------------------------------------------
     USER: ORT                       PRODUCT: PLACEBO
                               BATCH NUMBER: 1234
                                     MEDIUM: WASSER
    TARG. TEMP.: 37.0°C       BATH TEMPERATURE: 37.0°C
----------------------------------------------------------------------
BASKET 1  S/N 010309, BASKET TEMP.: 36.8°C

SAMPLE 1: DISINT. SINCE  0:00:25 A
SAMPLE 2: DISINT. SINCE  0:00:29 A
SAMPLE 3: DISINT. SINCE  0:00:43 A
SAMPLE 4: DISINT. SINCE  0:00:19 A (MINIMUM)
SAMPLE 5: DISINT. SINCE  0:00:47 A (MAXIMUM)
SAMPLE 6: DISINT. SINCE  0:00:33 A
----------------------------------------------------------------------
MEAN VAL. DISINT. TIME:      0:00:32
ABS. STANDARD DEVIATION:     0:00:10      _____
REL: STANDARD DEVIATION:     33.5%                 Signature
-----------------------------------------    ------------------------
                                         TIME  9:15:45  DATE 18.04.02
```