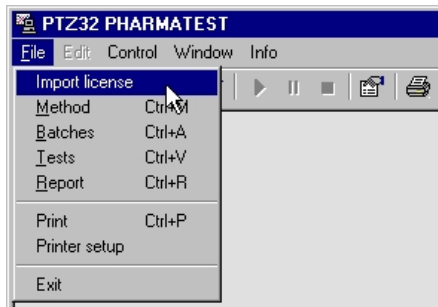


PTZ 32 - The Tablet Disintegration Test Software Package



The **PTZ32** software suite is an easily assimilated program with basic operating commands which offers the user a large range of data handling possibilities, especially when it comes to batch comparison. As you would expect the software has various controls applied and no experiment can be started and data accumulated without the user code and batch number being identified. This is in compliance with the latest FDA 21 CFR 11 proposals regarding data security. In addition, all accumulated data can be stored or printed in the original form but not altered within the PTZ32 framework.



The PTZ32 software from Pharma Test provides effective data and hardware management for tablet disintegration studies and Quality Control. It also includes a batch comparison statistics program, temperature recording and password protection.

The disintegration methods with automatic end-point detection require the use of the automated disintegration detection baskets PT-MKT or PT-MKT33. The PT-MKT baskets provide effective disintegration detection and continuous monitoring of the disintegration medium temperature (rather than just the bath temperature). The electronic baskets are universally applicable to almost all types of non-coated or coated tablets and capsules. These devices are essentially sample baskets with an electrical detection method such that once the tablet core or capsule does not provide an obstacle between the bottom of the basket (which contains a special metallic grid) and the disks (which contain an in built metal ring), a short circuit is detected and the period taken for this to happen is recorded as the disintegration time. The PT-MKT baskets are connected to the moving arm of the PTZ AUTO EZ Disintegration Tester. They are also electrically connected directly to the PTZ AUTO EZ instrument.

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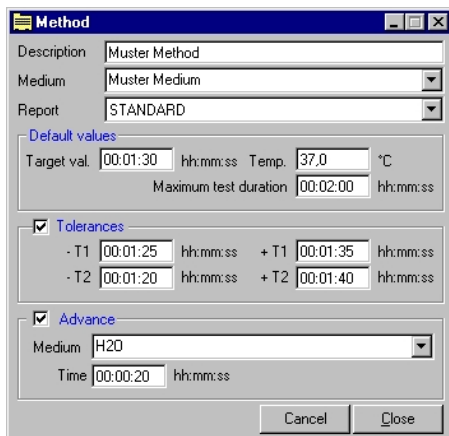
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The PTZ AUTO EZ instrument is also connected via an RS-232 or an USB adapter interface to the PC. The PTZ AUTO instrument can be started remotely from the PTZ32 software program. The software program works within a windows environment, version NT 4.0, 2000, or XP (US/GB versions). Each PT-MKT basket contains six tubes. When each station has reached the end point, then the PTZ AUTO EZ station will stop automatically. The individual disintegration times, plus a statistical calculation of mean value, minimum and maximum time are displayed. The software is presented in a format which is common to the other Pharma Test Software packages.

The PTZ32 software can handle multiple basket configurations (each station / basket with six samples). Each PT-MKT basket can operate independently. Methods can be constructed, stored and recalled for specific products. The bath temperature may be monitored as can the disintegration medium temperature with the PT-MKT basket. The only information required to start the instrument and therefore the data collection is the batch number and operator password / signature for identification and security. The windows presentation of the software is familiar to Pharma Test software users and includes list of results, statistics and graphics.

The menu bar contains five basic command positions: File, Control, Options, Window and Help. Of these, the first three are mainly used for routine control of the instrument's performance.

New Method:



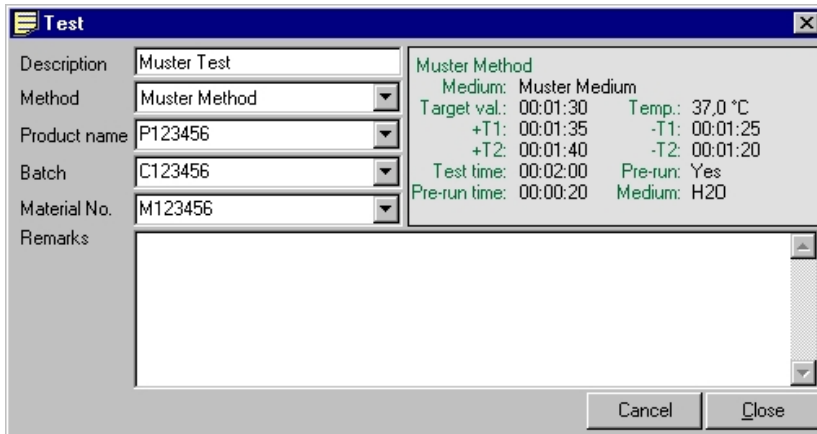
New methods can be easily developed by first clicking on the file box icon. The current method list for previously measured products will be shown. Click on "new" and familiar data entries can be made, which will be specific for your formulation. The following parameters can be defined:

1. Name of Method
2. Product
3. Form (can be pulled from memory if previously stored)
4. Medium (can be pulled from memory if previously stored)
5. Maximum testing time
6. Disintegration time limits: (min. and max.)
7. Pre-testing data (normally in alternative medium)

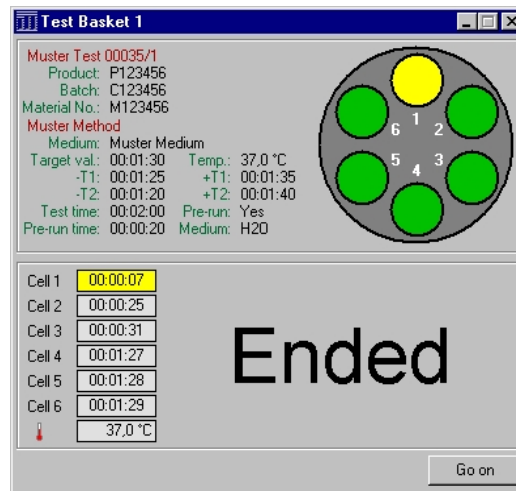
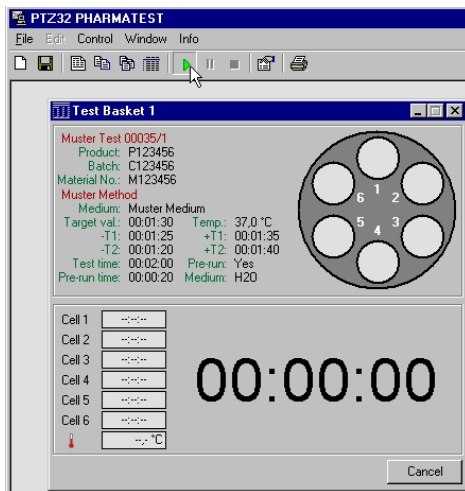
Just click on OK and the method is stored for future use.

Start an analysis:

Take the shortcut start alternative and use the corresponding Icon. You will be asked for the method which can be selected from the drop bar menu. Immediately all material data will be filled in. The only other data required is the batch number and operator password / signature. After this additional data can be entered such as the basket identification number (default is No. 1) and some commentary (remarks), if required.



Hit start and there will be a graphic display of the plan view of the basket with all six detection zones.

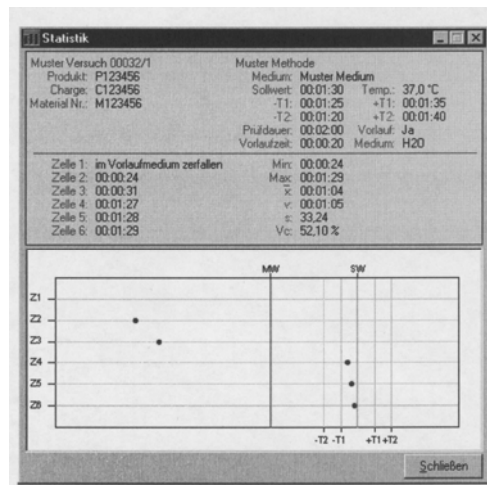


As each tablet completes its disintegration, the basket position will turn red and a corresponding time will be entered, which represents the time taken from the start of the analysis until the automatic end point detection.

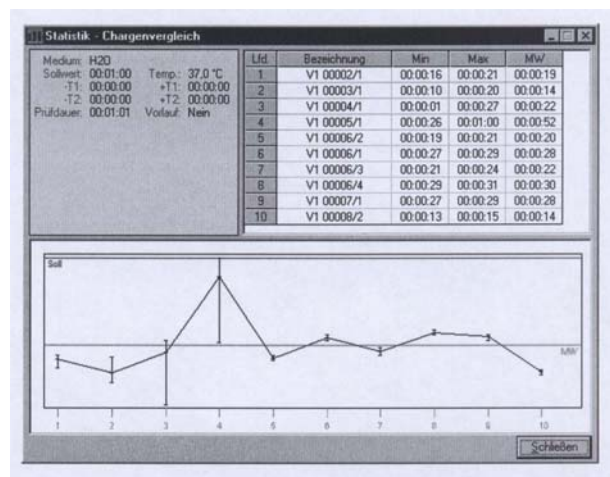
All results will now be displayed in tabular form with additional commentary boxes if required. Click on OK and the final presentation can be displayed and printed. This will contain the tabular data as well as a graphical presentation of the tablet disintegration times plotted between the maximum and minimum values allowed if these were programmed in the method selected.

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Test Result



Batch Comparison



Help Files:

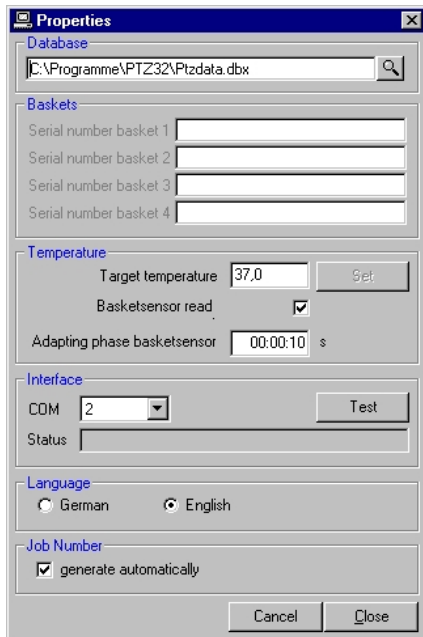
Help files are available under two headings:

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21CFR part 11 and GLP Integrity:



The software enables the system administrator to set and specify passwords for user rights, such as method and operational security. All data is immediately filed on the HDD for additional security.

A complete data file always includes test method information with full trace ability for the operator whenever results are recalled for inspection or subsequent printing. Original data cannot be changed or manipulated.

System and Software Validation:

Pharma Test develops and manufactures instruments and systems according to its operating ISO 9001 certified quality standard. The PTZ32 software is in full compliance to the 21CFR part 11 guidelines.

Installation and Qualification:

The PTZ AUTO Instrument Installation Qualification (IQ) and Operation Qualification (OQ) may be performed upon system installation by a trained Pharma Test engineer or representative.

PTZ32: A tablet disintegration data management software which can generate individual reports in both tabular and graphic formats.