> Dissolution Testing > Manual > Semi-Automated

ANALYTICAL

PRODUCT PROGRAM 2008/09

PHARMA TEST®

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PHARMA TEST

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EDITORIAL

PHARMA TEST ANALYTICAL PRODUCTS

In the current issues of our product guide, we separated the equipment range into three parts in order to make more detail available for each of the products offered. The Analytical brochure includes all equipment for manual Tablet Dissolution Testing, the Automated Dissolution brochure includes all online and offline Dissolution System, while the Galenic brochure includes all physical testing apparatus like hardness, disintegration, friability, etc. instruments. We hope that you find this convenient in terms of the information transfer. However, you still should log on to our WEB site and obtain further information and more technical details at: **www.pharma-test.com**

The products described in this brochure are essentially all of those which are dissolution based.
The product groups covered in this case are:

- DISSOLUTION TESTERS, IDEAL FOR MANUAL OPERATION
- DISSOLUTION TESTERS, ready for Automated Operation
- MEDIA PREPARATION
- ACCESSORIES for Dissolution Testing

DISSOLUTION TESTERS / MANUAL OPERATION:

All of the described standard dissolution instruments may be operated in this mode. Simple tablet addition to the prepared dissolution medium is all that is required with sample withdrawal made according to the relevant SOP (Standard Operating Procedure) and the current USP/EP pharmacopoeia for the formulation under test. All Dissolution Testers are able to be upgraded for either semi- or fully automated operation. See also the accessory section for manual sampling equipment as well as the range of standard accessories.

Dissolution Testers / Automated Operation:

All of our standard dissolution testers may be upgraded or delivered to operate within an automated Dissolution Test System. The basis of operation for this group is off-line operation using a pumped sample extraction system with a Fraction Collector or Auto-Sampler. An alternative for off-line automation is on-line automation in which the Dissolution Test Apparatus is connected to an Auto-Sampler and Injection System or directly to a UV/VIS Photometer offering resident or removable sampling probes.

We keep the right to make technical changes any time without prior notice

DISSOLUTION TESTER

PHARMA TEST DISSOLUTION TESTER - PT-DT70

PT-DT70 4+3 Vessels

The PT-DT70 is in full compliance with the relevant sections monographs USP<<717> and EP <2.9.3> as well as the Japanese Pharmacopoeia.
The PT-DT70 is the low head dissolution tester which provides a space saving, low cost entry into dissolution testing. Whether for a new laboratory or to meet tough budget requirements, the PT-DT70 offers a lot of instrument for a comparatively modest cost. This instrument offers seven stirred positions as well as a pneumatically supported lift off top for easy access to the dissolution vessels.
The dissolution vessels are placed in 2 rows (4+3) and are easily accessible to remove spent media and refill with solvent simply by lifting up the pneumatically assisted drive housing. To insert samples and withdraw sample solutions use the 7 tubes shafts which run through the top cover of the instrument. Simply place your tablets next to the holes and introduce them when ready to start. For easy sampling use the PT-MDS Manual Sampling System which includes a stainless steel sampling tube, an in-line filter and a 10 ml. disposable syringe. The PT-DT70 is already equipped with all necessary interfaces for easy integration into automated systems. The standard serial port can be used to connect a PT-DL Data-Logger reporting where the instrument serial number, date, time, tool speed and bath temperature can be recorded at programmable time intervals.

PROGRAMMABLE OPERATION FEATURES

- Stirring Speed
- Water bath temperature
- Alarm Signal, sampling time information
- Run time report printing (PT-DL needs to be connected to standard RS interface)

USP/EP STIRRERS

The Monoshaft™ stirring tools come in 2 parts; the stirring shaft which remains inside the drive chuck and the interchangeable stirring tool (Paddle, Mini Paddle, Basket, TC) which may be exchanged whenever needed without having to alter or revalidate the total length of the entire tool set (25mm±2mm required distance from vessel base is always maintained regardless of tool selection).

INDIVIDUAL LABELLING

Each stirrer shaft, stirring tool, vessel and vessel position has its own individual code to be easily identified and returned back into its qualified position inside the Dissolution Instrument.

WATER BATH AND AUTO CENTRING

The Plexiglas water bath is made from a preformed U-shaped single plate with a cross braced framework holding a PP cover into which the vessels are placed. Each vessel is automatically centred inside the cover and locked in position.

AUTOMATION

Within an automated system the PT-DT70 offers the operator full access to the vessels before and after the dissolution test as the complete drive housing effortlessly tips backwards thanks to the pneumatically assisted drive housing. The resident sample probes remain inside the dissolution head (drive housing). The PT-DT70 can be used for either on-line automation for online UV/VIS measurement or in conjunction with an LC system

The PT-DT 70 offers the following features:

7 Stirred positions. Additional vessel used for either blank or standard medium or for pre-warmed media replacement in case of fraction collector usage
"Low Head" Compact construction with small footprint
Pneumatic lift for raising head; easy access to tools and vessels
7 channels through the head allow tablet drop and manual sampling
Synchronous tablet drop magazine available
Electronic speed regulation from 20-250 rpm. Accuracy better than 4% of the nominal value, typically <1%
Bath and medium temperature range of 30-45°C; accuracy ± 0.2°C
Safety cut outs for over-temperature protection of heating element
LED displays for actual temperature and rpm
Integrated calibration program for rpm (tool speed) and temperature
RS 232 output to connect a data logger or for remote control in either on- or off-line applications
Full range of analytical tools available: stainless paddles, baskets, trans-dermal cylinders, paddle-over-disc and cream cells. Brown (UV) protected vessels also available
IQ and OQ paperwork included as standard with each delivery

For further information, download from our web site on:
www.pharma-test.com

PT-DT8S 4 + 4 Vessels

STAGGERED START, LOW HEAD ANALYSER, EASY TO QUALIFY AND MAINTAIN...

The PT-DT8S is a low head design, 8 dissolution vessel system for 6 samples, 1 stirred blank media and 1 stirred reference media vessel in a 4 + 4 system configuration. The stirring shafts are locked in position by individual and adjustable chucks which keep them securely in their qualified position. The stirring tools: Paddle, Mini Paddle, Basket or TC are screwed onto the stirring shaft and may be exchanged whenever needed without altering the total length of the entire tool set. The new Monoshaft™ designed stirring tools do not require any qualification when stirring tools are changed. The dissolution vessels are automatically centred within the water bath cover. The U-shaped water bath with its solid single frame holding the PP cover plate is rigid and safe in use.

PROGRAMMABLE OPERATION FEATURES

- Stirring speed
- Water bath temperature
- Alarm signal, sampling time information
- Sampling time information to control a Fraction Collector, for example PTFC-2
- Run time report printing (PT-DL data logger needs to be connected to standard RS interface)

STAGGERED STIRRER START OPTION

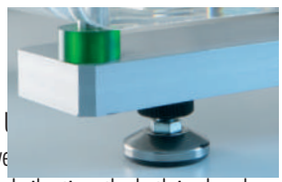
To perform a dissolution test manually, the staggered stirrer start option is usually the method of choice. At first, a sample is dropped into the first vessel when the media is at the correct temperature, as soon as the sample reaches the base of the vessel the stirrer should be started. After a short time period, the second sample should be introduced, with a sufficient time gap to enable sequential sample withdrawal. This way is possible to obtain samples representative of the same sample period. If the PT-DT8S operates as part of an automated system, it is possible to use the built-in standard Tablet Magazine to drop all tablets at the same time which permits the user to start all stirrers synchronously.

INDIVIDUAL LABELLING

Each stirring shaft, stirring tool, vessel and vessel position has its own individual code to be easily identified and returned back into its qualified position inside the Dissolution Instrument.

USP/EP STIRRERS

The Monoshaft™ stirring tools come in 2 parts; the stirring shaft which remains inside the drive chuck and the interchangeable stirring tool (Paddle, Mini Paddle, Basket, TC) which may be exchanged whenever needed without having to alter or revalidate the total length of the entire tool set (25mm ± 2mm the required distance from vessel base is always maintained regardless of tool selection).



VIBROBAN™ SHOCK ABSORBER, WATER BATH AND AUTO CENTRING

The Plexiglas water bath is made from a preformed U braced framework holding a PP cover into which the ve the dissolution process from any internal or external vibration, the bath is placed on to Vibroban™ shock absorbers. This unique design provides system vibration immunity far below the recommended levels stated in data from USP and various other publications. Even the built-in circulation pump is installed on a sprung-loaded platform to avoid vibration transfer to the dissolution vessels. Each vessel is automatically centred inside the cover and securely locked in position.

EASY ACCESS DRAWER DESIGN

Whenever the heating system or power electronics in the PT-DT8S needs to be qualified or serviced, the advantage of the Easy Access Drawer Design comes into its own. Its possible to service both without any need to move the bath from its qualified position; you save re-qualification and instrument down-time.

AUTOMATION

Within an automated system, the PT-DT8S offers the operator full access to the vessels before and at the end of a run as the complete head effortlessly tips backwards thanks to the pneumatically assisted drive housing. The PT-DT8S also offers the possibility for staggered stirrer start as well as a synchronous start. In the latter case, samples can be introduced by using the built-in Tablet Magazine. The resident sample probes remain inside the dissolution head (drive housing). The PT-DT8S can be used for either on-line automation for online UV/VIS measurement or in conjunction with an LC system.

OPTIONAL SET-UP

A Hollow Shaft version is available too. For automated sample withdrawel the sampling tubes are inside the hollow stirrer shaft, in this case no extra part will be inside the dissolution vessel during automated sampling.

The PT-DT8S main features:

8 Stirred positions. Staggered or Synchronous Stirrer start, additional vessels used for blank or standard medium or for pre-warmed media replacement in case of fraction collector usage.

"Low Head" Compact construction with small footprint - 80x55 cm

Tip back pneumatically assisted head lift for raising head; easy access to tools and vessels

Monoshaft™ stirrer design for Paddle, Mini Paddle, Basket, TC and rotating Transdermal as well as Cream Cell tools.

Adjustable stirring speed

Adjustable water bath temperature

Safety systems: lift the drive head = all stirrers stop; no pump flow = stop heater. Electronic over-heating protection supported by thermal fuse and thermo switch.

LED Display shows actual stirring speed and water bath temperature

Stainless steel instrument design, top cover has coloured powder coating

IQ and OQ documentation of the PT-DT8S included in the standard supply scope

For further information, download from our web site on:
www.pharma-test.com

TOP PERFORMANCE AT SENSIBLE PRICE

PTWS 310 The Trend Setting dissolution bath design

The PTWS 310 combines a compact design with state-of-the-art features and a comprehensive supply scope which includes a synchronous tablet drop magazine. The PTWS310 is secure in its handling and features the Monoshaft ™ stirrer tool design for all USP/EP stirring tools.

EASY MAINTENANCE... EASY AUTOMATION

Any operator of this class of instrument expects not only conformity with pharmacopoeia standards, but also easy operation and accessibility to the test vessels as well as a reduced need to re-qualify the instrument when stirrer tools are changed. This means that the dissolution bath should offer both good manual access as well as automation facilities. The PTWS 310 offers all of these features.

PROGRAMMABLE OPERATION FEATURES

- Password protected user access
- Administration of access rights such as run a dissolution test, qualify and calibrate the instrument, enter, edit or delete test descriptive data
- Stirring speed
- Water bath temperature
- Wake up and Sleeping Mode
- Alarm Signal and Sampling Sequence Information
- Start time for heating system (program the water bath warm up before the lab opens)
- Automated start of a dissolution run including tablet introduction (only when an auto tablet magazine is used)
- Programmable sampling positions inside the dissolution vessels
- OQ, PQ interval timing with reminders.

DISPLAY AND KEYBOARD

The PTWS 310 includes a large Graphic LC Display, 100x100mm and a alpha-numeric keypad, function keys and an optical status information ("traffic" light) system. The display will always show the target settings and the actual measured results, time, product and test information.

EASY TO ACCESS DISSOLUTION VESSELS

All dissolution vessels are placed in 4 + 4 configuration and it is easy to remove spent samples and refill with solvent. The clear-view U-shaped water bath and the central drainage tap ensures that the bath can be easily drained, cleaned and refilled when required. A built-in water diffuser distributes the heated media evenly throughout the bath. The central electric pillar lift raises the drive housing to provide sufficient space to remove, clean and replace the vessels quickly and securely. The standard instrument comes with 1 litre glass vessels but it is possible to install and work with mini-vessels too.

WATER BATH AND AUTO VESSEL CENTRING

The same quality design of "U-shaped" water bath, as is supplied with the PT-DT8S, is used for the PTWS 310. The vessels are placed into the PP cover and are automatically centred. This bath is also placed on Vibroban ™ shock absorbers. These same bath supports also allow levelling and adjustment during installation.

TABLET DROP MAGAZINE AND DISSOLUTION VESSEL COVER

The PTWS 310 comes with a tablet drop magazine for synchronous insertion of the samples into the dissolution vessels. The same magazine is also designed to effectively cover the vessels as soon as the samples have been dropped. A motorized tablet magazine system is available as an option. It is generally used when the PTWS 310 is integrated into an automated online or offline dissolution system.

USP/EP STIRRING TOOLS

Monoshaft ™ stirrers are also supplied with the PTWS 310. The stirring shaft is attached to the drive system with a safety chuck. The required stirring tool: Paddle, Mini Paddle, Basket or TC is screwed onto the stirring shaft without any change to the total length of the tool assembly. This way, the depth setting remains the same no matter which tool is used. The stirrers, as well as the dissolution vessel positions, are clearly and individually marked and batch coded.

OPERATOR AND OPERATIONAL SAFETY FEATURES

- Dual Hand operation of the motorized head drive
- Auto stop of the stirrers when the drive head is raised; it only operates in the qualified position
- Pressure switch to protect the pump system : no water flow = no pump or heater
- Electronic safety system to switch off the heating and pump system as soon as the temperature rises above the maximum permitted range; there is an thermal fuse and thermo switch too as back up to protect the heater system
- Low water-level switch to keep check of the correct water level inside the water bath

REPORTING AND PRINT OUT

A built-in thermo printer is used to report the instrument's operational performance during a test. Parameters such as water bath temperature, stirring speed and sampling times can be recorded. A OQ qualification report can be printed whenever this procedure has been performed.

For further information, download from our web site on:
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PTWS 310 Optional Equipment

EPE ELECTRONICALLY CONTROLLED AUTO SAMPLING SYSTEM

The PTWS 310 may be equipped with an EPE auto sampling system which will only lower the sampling probe into the dissolution vessels during the sampling sequence. Thereafter, it is raised back into its upper (home) position. The user can program the immersion depth and dwell time depending on the test requirements.

ITM INDIVIDUAL DISSOLUTION MEDIA TEMPERATURE MONITORING SYSTEM

If the EPE auto sampling system is installed, its possible to add the ITM device to read and record the actual dissolution media temperature during the sampling sequence. The results will be printed on the installed printer or may be transferred.

2 LITRE DISSOLUTION VESSEL VERSION

The PTWS 310-2 can be used for larger volumes of up to 2 litres of dissolution media. Of course the use of the more common 1 litre as well as Mini Vessels is possible in the 2 litre unit.

PH PROBE

A pH probe can be connected to the corresponding port of the PTWS 310. It can be used to measure and record the pH value of the dissolution media in each one of the vessels prior to a dissolution test and at the end of a run. The results can be printed and transferred.

PRODUCT AND TEST DESCRIPTION

The standard instrument permits the entry of information as to how the test should be carried out and this information can be filed for subsequent runs. The memory space is limited but can be extended using the expansion USB memory system.

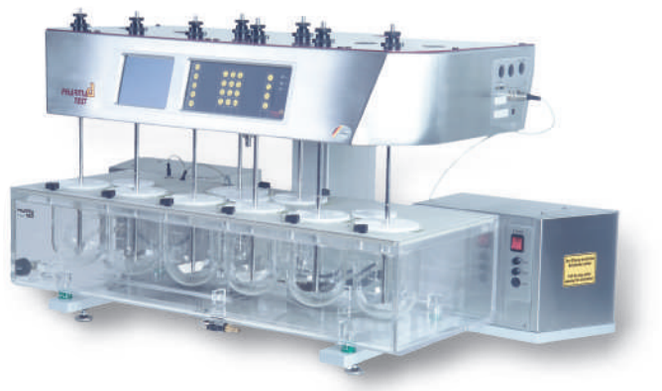
AUTOMATION

At the basic level, a PTWS 310 can directly control a PTFC-2 Fraction Collector and a Pump, for example, in a typical "Off-Line" application. All necessary information for sample collection, medium replenishment and so on is entered as a test description using the Keypad and LC Display of the dissolution tester. Whenever this system is ready to be started, just press START and the automated sample collection sequence begins. As the PTWS 310 is already equipped with a communication port it can easily incorporated into a fully automated online UV or UV/HPLC system.

The PTWS 310 main features:

The PTWS dissolution tester family is in total compliance with the specifications of the USP <711> and EP <2.9.3 + 2.9.4> monographs.
It is possible to use the PTSW 0 Rotating Suppository Dialysis Cells to test the dissolution profile of suppositories and other lypophilic API carriers.
Auto control centre for speed, temperature, water level and pump flow.
Vertical and horizontal adjustment facilities for the instrument frame work and the water bath
Stirring tool depth qualification using easy to handle certified calibration spheres.
Accessory set available to use Mini Dissolution paddle and vessel sets.
Reduced vibration inside the dissolution instrument from internal and external sources via the use of Vibroban™ shock absorber design and vibration suppression assembly of the pump and heating system.
Integrated water diffuser for faster warm up and better heat distribution
Central pillar head lift for easy vessel access and rapid tool exchange
Reduced heating time due to new design of heating system hardware
Built-in Report Printer
Qualification and Calibration menu for tool rotation speed, bath temperature, ITM media temperature system, pH probe and EPE sampling positions
RS232/USB port
Compact design - 80 x 55 cm
Instrument body made from stainless steel; top cover is powder coated
IQ and OQ documentation of the PTWS 310 included in the supply scope as standard

PTWS 610 6 In Line Design Staggered Stirrer Start Option



A TRIED AND TESTED DESIGN

The PTWS 610 is a member of the PTWS instrument family and so the technical specifications equal those of the PTWS 310. The 6 in line design eases the manual sampling and media refilling procedure as the dissolution vessels are directly in front of the user. The 2 extra dissolution vessels may be used to contain a Placebo, Blank or Reference Standard media. The central pillar lift, vibration proofed installation of the water bath and heating system, LCD monitor, alpha-numerical keyboard, auto control centre, easy access drawer for pump, heater and power electronics and the built-in report printer make the PTWS 610 the ideal instrument for manual dissolution testing. Even so, it is always possible to integrate the PTWS 610 into a fully automated online or offline dissolution system.

STAGGERED STIRRER START OPTION

Whenever manual sampling is needed, a dissolution bath should offer easy access, delayed (staggered) start of each stirring position as well as a perfect visual view of the dissolution process during the test. The PTWS 610 is the ideal tool for this type of dissolution requirement. The staggered start feature makes sampling easier and allows the user to comply with the USP 2% sampling time restrictions. The PTWS 610 includes these and many more technical features as already described above for the PTWS series. The vessels are covered by individual covers having openings to take sample probes, temperature sensors or pH probes

It goes without saying that the PTWS 610 can be operated in a synchronous start mode; if this is a system requirement we offer a manual or electrically controlled tablet drop magazine.

PTWS 1210 12 Positions, ideal for Bio-waiver studies and greater throughput

The PTWS 1210 offers a massive 12 sample throughput for busy labs and those wishing to complete Q1 and Q2 result levels in one test. This bath design offers the same physical conditions for all 12 samples inside the dissolution vessels: the same tool speed, same temperature and the same immunity to both internal and external potential vibration sources. The instrument not only complies with all requirements listed in the Pharmacopoeias but also includes Vibroban™ Vibration Absorbers to avoid vibration influences coming from the test laboratory environment. The importance and impact of vibration effects on Dissolution Testing has been the subject of many publications.

ADVANTAGES USING THE PTWS 1210 DISSOLUTION TESTER

- Big Time Saver: get results in half the time it takes to run tests on two separate baths
- Eliminates Variability, there are no temperature, stirring speed or start point variations in one 12 vessel PTWS1210 bath, as compared to the potential variability for two separate 6, 7 or 8 Vessel Dissolution Testers.
- Less maintenance work, less documentation, only 1 instrument to calibrate and validate instead of 2
- Space Saver: much smaller foot print as compared to two 6, 7 or 8 Vessel Dissolution Testers

The PTWS 610/1210 main features:

Auto-Control station for checking tool speed, bath temperature, bath water level and the operation of the pump and heating system.
Vertical and horizontal adjustments for instrument and water bath
Auto centring feature for all vessels
Built-in report printer includes online documentation for tool speed, bath temperature, media temperature (if EPE and ITM are installed), sampling times and instrument data
Easy and fast access drawer design for pump, heater and power electronics maintenance.
Programmable sampling position if EPE is installed
Programmable heater start and stop ("sleep and wake up" mode)
Programmable position of central lift pillar enables the user to set a cleaning position and head height for special tool types (e.g., Suppository Dissolution Accessory: PTSW 0), etc.
Central pillar lift to raise the drive head for quick and easy cleaning as well as tool change
Electronic and electrical safety devices for heating system and water pump security
Memory for product and test descriptions: can be extended to an unlimited number using an USB memory stick
Calibration and adjustment program for stirrer speed, bath and media temperature, pH probe, immersion depth and sampling position of EPE system
RS232/USB port for external instrument control
Programmable OQ and PQ interval including user information
Instrument status information – "traffic light" system
Compact design, only 120x55 cm for 12 vessel dissolution bath
IQ and OQ instrument documentation included in standard supply scope

PTWS D610 Dual Stirrer Drive, 2 x 6 vessels

Using the PTWS D610 its possible to run a dissolution test on the same or different batches even using different tool speeds or tool types within the same instrument framework. Two LC Displays and a single keyboard are used to enter and check all set-up information. Of course, should the need arise both sets of stirrers can be run at the same speed and with the same tools, should this be required.

THE PTWS D610 MAIN FEATURES

- Individual stirring speed control for 2 x 6 stirrers
- 2 LCD screens and 1 keyboard to enter test data
- Common heating system
- Individual dissolution vessel covers

All other technical details are exactly the same as previously described for the PTWS 1210.

OPTIONAL EQUIPMENT

The PTWS 1210 and PTWS D610 can be supplied with a variety of optional equipment; below, we describe some of the most popular options.

EPE AUTO SAMPLING SYSTEM

A common EPE auto sampling system for all 12 vessels can be added to the PTWS 1210 and PTWS D610. The sampling probes will only stay inside the dissolution media while a sample is withdrawn and then return into the upper home position.

ITM INDIVIDUAL TEMPERATURE MONITORING SYSTEM

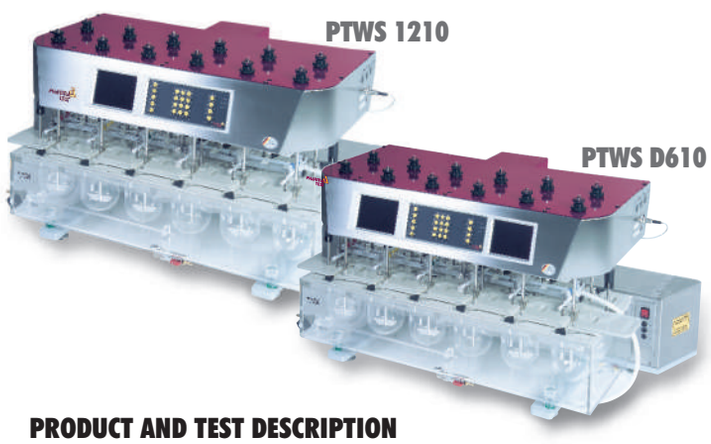
If an EPE is installed to the PTWS 1210 and PTWS D610, the ITM system may also be incorporated. The media temperature will be monitored, printed or transferred (via interface) while a sample is withdrawn from the dissolution vessel.

TABLET DROP MAGAZINE

A tablet drop magazine should be used if an EPE auto sampling system is to be used. The tablet drop magazine will drop all dosage form samples synchronously into 6 or all 12 dissolution vessels.

PH PROBE

The pH probe can be used to monitor the pH value of each dissolution vessel prior to and after a tablet dissolution run.



PRODUCT AND TEST DESCRIPTION

As with all members of the PTWS family, the product and test description can be filed in the standard PTWS D610 dissolution bath. Unlimited memory is available if the USB option is installed.

DISSOLUTION AUTOMATION

Each one of the 2 stirrer sets can be externally controlled via the built-in RS232/USB port. The PTWS 1210 and PTWS D610 can also directly control a PTFC-12 Fraction collector, but sampling times need to be the same for both stirrer sets. The WinDiss32 Software allows the user to integrate this dissolution bath into a fully automated online or offline dissolution test system.

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PTWS 4000 Pool Test Application

The PTWS 4000 is a specialised 4-litre dissolution tester version that enables the user to perform either pooled tests, or test for dosage forms that contain high concentrations of active material. The instrument is supplied with 6 stirred 4 litre and 2 unstirred 1 litre dissolution vessels. This instrument can also be adapted to handle 2 litre and 1 litre vessels.

The instrument control is the same as for all other PTWS instruments described above but the frame work is substantially different. 2 lift pillars are used to move the upper head housing. Staggered and synchronous stirrer start is possible. The system comes in a stainless steel design which is one of the highlights of this instrument.

OPTIONAL EQUIPMENT

Not all available options for the PTWS series can be used with the PTWS 4000. Its not possible to add an EPE auto sampling system or ITM; a Tablet Drop magazine is not available. Each 4 litre vessel has its own individual vessel cover.

PH PROBE

The pH probe can be used to measure the pH value prior to and after a dissolution run.

PRODUCT AND TEST DESCRIPTION

As for all PTWS instruments, the standard supply scope includes the possibility to enter several product and test descriptions. Using the USB option this can be enhanced to an almost unlimited memory capacity.

DISSOLUTION AUTOMATION

The PTWS 4000 can also be integrated into a fully automated online or offline dissolution system using the WinDiss32 software suite. There is also a driver available which will allow the use of this bath with Agilent Chemstation Station software.

PTWS 4000 main features:

Auto Control Station for tool speed, temperature, water level within the water bath, pump and heater system supervision.
Vertical and horizontal adjustment of the instrument mainframe and water bath
Solid U-shaped, cross-braced water bath design; single frame to hold the PP water bath cover which includes the vessel auto centring design.
2 lift pillars to drive the upper head assembly smoothly up and down for easy vessel removal and cleaning, or stirrer tool change.
Space requirement 140 x 60 cm

PTSW 0 Rotating Dialysis Cell for Suppository Dissolution Testing

The PTSW 0 can be used to test the dissolution rate of suppositories and other lipophilic samples as well as gel capsules. It can not only be incorporated into any PTWS tablet dissolution bath offering staggered stirrer start (PTWS 610/1210/D610/4000), but also into the PTWS 310. The drive of the rotating cell is attached to the individual stirrer shafts of the dissolution bath while the built-in gearbox of the PTSW 0 reduces the nominal tool speed in the ratio of 4:1.

The sample is placed into the cell together with about 5 ml of dissolution media. The cell is sealed and the complete instrument is placed into a standard USP/EP dissolution glass vessel. This is usually filled with water at 37°C. The active material will diffuse out through the membrane which covers the cell into the outer media, leaving bulking agents, such as wax or cocoa butter, behind.

Sampling and measuring of the active content can be carried out by using a standard stainless sampling probe; no additional filter needs to be used.

PTWS 0 main features:

Can be used with all PTWS 310/610/1210/D610 and PTWS 4000 dissolution test instruments
Standard supplies includes 10 membranes

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DISSOLUTION MEDIA PREPARATION AND DOSING INSTRUMENT

The USP Reference Standard Tablets (formerly referred to as calibrator tablets), are used to perform a dissolution instrument suitability test after a successful physical parameter qualification (OQ). During this suitability test, the quality of degassing has a significant effect upon the test results obtained; so does vibration. Naturally, the mechanical "fitness" of the instrument has to be established and is usually achieved by performing the OQ prior to the USP suitability test. Low vibration level, low wobble, correct tool centring and precise tool depth setting are just some of the factors which may affect a successful qualification; but media degassing is one of the most influential factors.

PT-DDS 4 De-aeration and Dosing of Prepared Media

The PT-DDS Media Preparation System has proven in many tests and in general operation, that its automated degassing and dosing procedure fulfils the requirements of both the FDA and USP and that USP dissolution qualification test will be successfully achieved.

The prepared media (water or buffer) can either be filled directly into the media tank or it can be automatically primed using the on-board vacuum pump and the internal liquid level sensor which controls the pre-filling volume. Select the method of your choice and enter the maximum volume. It is also possible to mix a buffer using demineralised water and a buffer concentrate if the on-line buffer mix option is installed.

The instrument's Keyboard and LC Display are used to file product and de-aeration information. Enter and file descriptive data for the number of media doses required, user data, media information and so on. All method related data as well as the dosage reports can be saved to hard copy using the built-in printer. A maximum 16 product and de-aeration method files can be saved and stored.

As soon as all data are entered, the de-aeration process can start. While the media is heated, it is constantly circulated under vacuum within the tank. The de-aeration process needs about 30 - 45 minutes for ca. 25 litre of media. Thereafter, 25 litres of de-aerated and pre-heated media is available for either gravimetric or volumetric dosing. Volumetric dosing will allow on-line dispensing directly into the dissolution vessels.

GRAVIMETRIC DOSING

The PT-DDS4 is equipped, as standard, with a built-in load cell which is used to precisely measure the dosing volume. It is also used to qualify and adjust the dosing accuracy. A dissolution vessel holder supports the empty vessel beneath the dosing tube. Select the media volume to be dispensed and start dosing as soon as de-aeration process is finished. The number of medium dosages as well as the actual dosed volume and any deviation from target volume is reported on the built-in printer.

VOLUMETRIC DOSING

Dispense de-aerated media directly into the dissolution vessels while still inside a dissolution bath using the liquid flow sensing system for precise dispensing. Place the dispensing tube into the vessel and dispense the media with the push of one button.

VOLUME SELECTION

Select any volume to be dispensed up to 5000 ml

CLEANING AND MEDIUM CHANGE OVER

Call up the preset cleaning program to assist with system cleaning and rinsing. The stainless steel tank, all tubing connections and dispensing lines will be flushed.

EASY QUALIFICATION AND CALIBRATION

The PT-DDS 4 includes an integrated qualification and calibration procedure which does not require any external instrumentation other than a certified 1000 g weight. Both versions of media dosing are qualified using the certified weight which leads to a dosing precision of better than 1% which is allowed under USP rules governing media dispensing. The qualification and calibration results can also be printed.

PT-DDS 4 main features:

- *The PT-DDS complies with USP, EP and FDA requirements*
- *It holds de-aerated and pre-heated media for up to 24 dissolution vessels*
- *The menu driven information centre guides the user for dosing and calibration data entry*
- *LC Display and alpha-numeric keypad for data entry and user information*
- *Memory to file de-aeration and dosing information for 16 different media types*
- *Integrated cleaning program*
- *Integrated qualification and calibration program*
- *Mobile design can be used in any laboratory*
- *Print-out and data transfer*
- *Optional accessory for online vessel filling and buffer preparation*
- *Fast return on investment (ROI) time, pre-heated and de-aerated media saves time normally wasted waiting for medium warm up and increases productivity.*

For further information, download from our web site on:
www.pharma-test.com

ACCESSORIES

PHARMA TEST ACCESSORIES FOR DISSOLUTION TESTERS

We offer a full range of accessories for dissolution testing based on the requirements stated in the international Pharmacopoeias. We are able to present only a sample of the total range, so if you do not find what you need please either contact us directly or visit our web site for further information.

DISSOLUTION VESSELS 250ml, 1ltr., 2 ltr., 4 ltr.

In clear glass or UV protected brown glass, with volume graduations.

DISSOLUTION TOOLS

Paddles (USP App. 2) in stainless steel, Teflon coated or gold plated. Baskets (USP App. 1) in stainless steel or gold plated. Baskets supplied in 10, 40 or 100 mesh options. Mini paddles in stainless steel, Paddle over Disk (USP App. 5), Rotating Cylinders (USP App. 6), cream test cells, suppository dissolution cells, intrinsic dissolution accessory; all tool shafts are batch coded.

Intrinsic Dissolution Accessory

Paddle Over Disks

Paddles in stainless steel

Rotating Cylinders

Stirrer Testing Station SWT2

BASKETS (Apparatus 1)

Available in various mesh sizes, either in stainless or gold plated

SINKERS

We offer a large variety of tablet and capsule sinkers in various forms and finishes. We have a range of paddle and basket depth gauges, manual sampling systems, in-line filters with 5 or 10m pore sizes, water diffusers for even heating of water baths, flow through cells (USP Apparatus 4), USP Calibrator Tablets and standards.

3 Turn Large Capsule Teflon Coated Sinker

Time Release Tablet Sinker

6 Turn Small Capsule Teflon Coated Sinker

3 Turn Large Capsule Stainless Steel Sinker

6 Turn Small Capsule Stainless Steel Sinker

Jap. Pharm. Capsule Sinker

Combined Centring and Depth Gauges for USP App. 1 and 2

ACCESSORIES for Dissolution Testers

We cannot show our full range of accessories due to space restrictions, but you can see a full range of these items on our web site.

For further information, download from our web site on:
www.pharma-test.com

PHARMA TEST ALL OVER THE WORLD...

With over 70 distributors and agents serving your interests world-wide, with fully qualified and trained staff to service and maintain your investment.

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