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# PHARMA TEST Journal

Issue 01/08

**PHARMA TEST is proud to present you the latest issue of the PHARMA TEST Journal.**

## Topics covered in this journal:

1. About Biowaiver Studies and Why the PTWS 1210 is the Optimal Solution p. 2
2. The Influence of Vibration on Dissolution Tests p. 4
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## Recent Developments in Our Product Portfolio

### Vibration Absorbers in PTWS Instruments

The instruments of the PTWS and DT8S series now all include Vibration Absorbers to improve the stability of the dissolution measurements. We are already getting very good feedback from our customers using this kind of vibration reduction. Several publications have clearly shown the high dependency between vibrations and dissolution rates and confirm our research results. You will find more on this in the article "The Influence of Vibration on Dissolution Tests" on page 4 in this issue of the PHARMA TEST Journal.



### A New Solution for Biowaiver Tests



The PTWS 1210 is now used in several labs to perform so called Biowaiver tests to decrease costs for clinical trials. The FDA has now allowed the testing of a multitude of generic drugs in Vitro with 12 tablets instead of performing a costly in Vivo test with humans. You can read more on this in the article "About Biowaiver Studies and Why the PTWS 1210 is the Optimal Solution" on page 2 in this issue of the PHARMA TEST Journal.

### Major Update of the WHT32 Software Package with Added Functionality

The WHT32 Software Package has been designed to be able to perform tests according to EP 2.9.5 (Mass Uniformity Tests). Other important changes are also implemented to improve the user-friendliness and facilities. Furthermore it is now possible to perform hard gel capsule tests (empty caps – filled caps – filling weight).



For more information on new developments see also the "Exhibition Forecast: Analytica 2008, Munich" article on page 9 of this issue.

## About Biowaiver Studies and Why the PTWS 1210 is the Optimal Solution

Under certain circumstances in-vivo studies may be replaced by in-vitro dissolution testing. This is referred to as a "Biowaiver". In order for this substitution to be possible, it has to be allowed by regulatory authorities. Biowaiver studies offer enormous cost saving potentials: while costs of approximately \$300,000 are common for a BE study with in-vivo tests, a Biowaiver study's costs can be as low as approximately \$2,000.

In order to able to realize these potentials the following requirements have to be met:

1. Allowance of regulatory authorities like FDA, WHO etc. The drugs should have a high solubility and a high permeability according to the biopharmaceutics classification system (BCS I). Other classification systems are part of current investigations
2. Dissolution test in three different media (A. Buffer pH 1.2, SGF without enzymes or 0.1N HCl, B. Buffer pH 4.5, C. Buffer pH 6.8 or SIF without enzymes) all in 900ml and at 37°C
3. Twelve samples in each media, Paddle 50rpm or Basket 100rpm
4. Sampling time: 10, 15, 20, 30, 45 and 60 minutes
5. The profiles of the test and reference products (for example original tablets if generic products are tested) must be similar (see point 6) in all three media
6. The products are similar if the factor  $f_2 \geq 50$  and both products show  $\geq 85\%$  dissolution in 15 min

This is the official statement of the FDA regarding this issue:

**FDA Guidance for Industry:**  
*"Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System"*  
<http://www.fda.gov/CDER/GUIDANCE/3618fnl.pdf>

### The Optimal Solution for a Biowaiver Study is the PHARMA TEST Twelve Vessel PTWS 1210 Dissolution System

The PHARMA TEST PTWS1210 dissolution tester offers twelve vessels in one bath. The instrument complies with all requirements given by the Pharmacopoeias.



On of the main advantages of the PTWS 1210 twelve vessel dissolution tester is that it saves a huge amount of time. Compared to tests running on two separate baths, this system delivers results after only half of the amount of time:

Biowaiver Test (1 hour)	Conventional Dissolution Test (6 Vessel Bath)	PTWS 1210 Test (12 Vessel Bath)
3 x Product Test	6hrs	3hrs
3 x Reference Test	6hrs	3hrs
Time needed	12hrs	6hrs

Furthermore the PTWS 1210 is a lot less expensive compared to the cost of two six, seven or eight vessel dissolution testers. It also eliminates variability, as there are no temperature, stirring speed or start point variations in one twelve vessel PTWS 1210 bath compared to the variability of two separate six, seven or eight vessel dissolution testers. Choosing the PTWS 1210 results in less work and even less amount of necessary documentation. This factor is strengthened due to the benefit of having only one instrument to calibrate and to validate instead of two individual systems. The PTWS 1210 saves space as the foot print is much smaller than the one of two six, seven or eight vessel dissolution testers. The instrument is essentially vibration free, as the PTWS 1210 has patented Vibroban shock absorbers to eliminate any instrumental or environmental vibrations that may affect the dissolution rate.

For further information on this issue also have a look at the article "The Influence of Vibration on Dissolution Tests" on page 4 of this issue of the PHARMA TEST Journal. The impact of the effects of vibration on dissolution tests is also published in the magazine "Dissolution Technologies" in the issue of May 2006 on page 8, under the title "Challenges to the Dissolution Test, including Equipment Calibration" authored by Mrs. Vivian Gray.

For your convenience please find some extracts from this article below:

*"...Historically, the calibrator tablets were developed because representatives from the FDA, USP, and the Pharmaceutical Manufacturers of America (now PhRMA) all agreed that vibration (internal and external) was influencing the dissolution results of products..."*

*"...It is well documented that vibration affects the dissolution results; in some cases, vibration biases the results high, giving a false passing result..."*

*"...We must also acknowledge that not all equipment on the global market is solidly designed..."*



**PHARMA TEST ...WE KNOW HOW!**

**Out of Specification Dissolution Profiles?  
Excessive Vibration could be the problem.**

Introducing PTWS New Generation Dissolution Testers:

- Innovative, Unique Vibration Elimination Features
- No noisy External Heater/Circulators
- Patented Environmental Vibration Suppressors
- Instrument performance better than proposed PhRMA/FDA limits!

**Ask for our Technical Bulletin Today!**

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## The Influence of Vibration on Dissolution Tests

It has become apparent in the recent past, that vibration within the Tablet Dissolution testing environment is a real issue. Although this may not have been too apparent in the normal routine dissolution testing, the real impact of vibration has become a focal point as a result of the Prednisone "Calibrator Tablet" tests which generally have to be performed every 6 months on each instrument within the testing environment. Prednisone tablets are referred to as "Disintegrating" tablets as they break down in the medium very quickly to form a powdered mass, either in the basket (Apparatus 1) or as a fairly well defined cone under the Paddle (Apparatus 2). The second system validation test is made using Salicylic Acid tablets which are "non-disintegrating", so they keep their form throughout the test and just dissolve away slowly.

The Prednisone tablet is 10mg in active content and so it has a large percentage of excipients present; in contrast, the Salicylic Acid tablet is made entirely of Salicylic Acid with no excipients present.

### What can go wrong?

The discussion will be limited to the Prednisone tablets as their dissolution rate is more affected by the vibration issues under discussion. However, the influences of the sources outlined below can have an effect on all types of dissolution tests and their influences cannot always be absolutely defined. Their elimination or minimisation however, will lead to a corresponding reduction in systematic errors, which is to be desired.

Up to this point, there were certain "anomalies" noted with Prednisone tests and a lot of the more spurious results that were obtained as a result of these tests were put down to various causes, normally the quality of the Tablets themselves. Shooting the messenger seemed to be an easy option in some quarters. The issue of test reliability appeared to become a particular problem when the formulation was changed from a 50mg tablet to a 10mg tablet. Up to this point there were no particular influences noted with the 50mg formulation. The 10mg formulation however, presented some challenges to the operator and his / her working environment and it became apparent that the dissolution release rate was greatly influenced by two main factors:

- Dissolved gasses, and
- Vibration

On many occasions, the combination of poor de-aeration and vibration can work together to produce all manner of strange effects. The dissolved gasses issue can be easily resolved using a suitable de-aeration technique. At this point it is reasonable to draw a difference between "degassing" and "de-aeration". Degassing is a technique whereby dissolved gases with a high solubility product can be displaced by dissolving in a gas with a lower solubility product. Typically, Helium can be used to displace both Nitrogen and Oxygen in aqueous media. De-aeration, on the other hand, is a method by which we can physically remove the dissolved gasses from the medium. If we follow the USP requirements, then this can be achieved by a combination of heating, vacuum and circulation (ref.1). Medium de-aeration today is a well defined subject and should not be an issue.

### So this takes care of the De-aeration issue. What about Vibration?

Vibration sources can be very diverse in origin. Some of the sources are listed below:

- Internal sources
- External sources
- Intermittent and operational sources

### Internal Sources

#### The Heater / Circulator

These basically arise from the instrument construction and the types of components used to manufacture the machine. The first major source is that of the external heater /circulator. These devices are normally of a basic design with a reasonably powered pump which takes water from the bath, circulates it through a heater element and then returns it to the bath. Unfortunately this is one of the least developed parts of the instrument package and therefore because of the generally "low cost" design are not in any way vibration proofed and sit on the work bench beside the dissolution bath and rumble away. These devices generate a lot of 50/60Hz noise which is transmitted through to the dissolution bath. The construction of the lab bench can also prove to be an amplifier for this "transmission".

#### The Drive Motor

The next source is that of the tool rotational motor, drive belts and bearings. The rotational motor can be a source of vibration. It normally is a DC motor with a gearbox attached. The

gearbox has to be maintained and checked for squeaks and rattles.

### The Drive Belts

The drive belts fall into two classes: those which are expected to drive all tool shafts from a single belt and those which have a high contact angle with the drive shaft mechanism (so multiple belt drives). Generally, the quality of the belt will play a big role in the generation of higher frequency vibration which is then transmitted down the tool shaft which adds another enforced dimension to the tablet disintegration and dissolution process. Noise generated in this way will turn the tool shaft into a type of ultrasonic disintegration probe resulting in higher dissolution rates, especially for Apparatus 1 baskets. The effect is not so profound with Apparatus 2 paddles, probably due to the relative dissociation of the tool and the tablet and the damping effect of the medium. Using Prednisone with Apparatus 1, you can tell if there has been significant high frequency vibration transmission by the amount of "escaped" powder at the base of the dissolution vessel. Inspection of the belts will show immediately if there has been some wear and if they are shiny, then the impact on the metal or plastic drive cog wheels at the top of tool shaft will be to generate noise. You can either replace the belts or use a silicone grease based PTFE loaded spray (sparingly) which will smooth out the noise. The effect of this type of loaded lubricant can be quite dramatic.

### The Bearings

The bearings themselves can be either lubricated for life or grease packed (generally in older models). The bearings are not generally checked for wear and tear themselves but are tested as a function of the tool wobble or run-out test which is part of the OQ procedure. Of course there is the need to distinguish between tool wobble and bearing induced wobble. The bearing contribution to the overall wobble can be easily measured at the part of the tool which passes through the bearing and is located at the top of the dissolution tester head. If the tools are in a sealed ("capped") bearing then this is not possible. Your only guide will then be the wobble or run out at the end of the tool shaft. However, the bearing/tool wobble may not be totally indicative of bearing noise. Wobble measurements may not show up sporadic bearing noise (typically a low frequency knocking). This can influence the dissolution rate very significantly especially with Apparatus 1 baskets. Excessive tool wobble may be indicative of distorted tools or worn bearings. An experienced investigator will be able to feel and pin point any unusual bearing behaviour.

### External Sources

So this is the mechanical side; but what about the environment directly around the instrument? Almost no attention is paid to environmental sources. Only on some rare occasions is there such an influence that the lab is more or less forced to concede that there have been hidden forces at work.

A typical example was that of a 12 position bath placed in a laboratory where most of the instrument was resting on an old weighing table (so really stable) and the rest of the instrument (about the last 1/3) was resting on an extension to this weighing table which was made from "kitchen" style worktop with a thin metal frame as a support. During the Prednisone tests it was noted 3 times that vessels 5 and 6 as well as 11 and 12 were failing the test when 1, 2, 3 and 4 in the front row as well as 7, 8, 9 and 10 in the back row were well within the range. The answer was a BET Surface Area Analyser which uses a high vacuum pump to de-gas powdered samples prior to analysis. The pump is running more or less full time and from experience, is usually the least serviced part of the instrument system. The pump was resting on the floor but only about 0.5 metres from the base of the frame support. The vibration transmission was easily spotted in the poorly supported dissolution vessels as a series of concentric ring patterns in the surface of the media. With the pump off, all was well.

This was by no means, the only potential culprit. Old fridges with ancient compressors are also a good source.

### Intermittent and Operational Sources

The trouble with any intermittent problem is that it is just that, i.e., it may not always be there. The best example is the slamming door. Portable A/C units can also be a problem.

Intermittent sources can also be operator generated. Some instruments have electric head drives (to raise and lower the head) and some are manually operated, either with a pneumatically assisted swing head or with a guided vertical drop. Both of these mechanisms can be sources of problems if not smoothly placed into the operating position. This again, is particularly the case with Apparatus 1 baskets. Sudden movements while the Prednisone Tablet is in the process of disintegrating can fire a shower of tablet material out of the basket and into the medium. A failed test is not far off. With swing head which opens and closes with a movement through approximately 135°, a slow gentle placing of the head in the working position will avoid problems. This situation

seems to have greatly improved with the transition to the new LOT POE203 from the previous OOC056 LOT. Values for baskets also appear to be much tighter in range.

With the vertical drop mechanisms, there is a tendency for the drive way to be a little harsh in its transition into the working position. Additional pressure to move the head can result in a hard hitting arrival which again, will drive more of the disintegrating formulation out from a basket than should be allowed for a successful test.

### So what can modern dissolution tester designer do for you regarding Vibration?

Modern test instrument design using up-to-date materials should be designed with the dissolution user in mind and not just for cheap construction. As far as the USP is concerned it has been noted that there is only a brief mention of vibration requirements consisting of the statement that “no part of the assembly, including the environment in which the assembly is placed, contributes significant motion, agitation or vibration beyond that due to the smoothly rotating stirring element” (ref. 3).

Other publications have also been mindful of the potential errors in terms of dissolution testing and amongst the biggest influences were vibration and medium de-aeration (ref.4).

Various studies have been carried out to try and quantify the effects of vibration on the resulting release rate of Prednisone tablets in particular. Some co-workers have also carried out exhaustive tests in order to investigate the effects of vibration on both older and newer instrument types and to provide definitive proof that the introduction of some critical design features can result in instruments that are the most developed available and that they represent a truly foresighted view of the future requirements of the dissolution user.

The total findings regarding our investigations are available upon request (ref.5).

The effect of vibration on instruments from various suppliers has also been investigated and is documented in existing literature (ref. 3). The method of vibration analysis and investigation was also reviewed by this independent body and the results make quite interesting reading. The main points are that:

1. How you measure vibration and how you quote it is important.
2. Are you measuring vibration in one axis or are some axes being “damped”?

3. It is important to use a real vibration meter which is sensitive to vibration in all axes, rather than just one which simply fixes on to the instrument surface.
4. Some newer instruments that are supposed to be state-of-the-art are more susceptible to vibration on their results than some older or less expensive units (see comparison of the newer VK7025 with older Distek 2100 and VK7000 series units).

### What is different about these instruments with the newer critical design features?

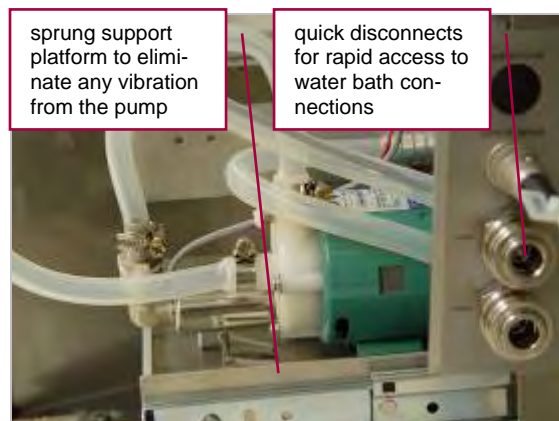
The main differences come from the quality of construction and detailed research aimed at making a better all round instrument that is already prepared for all the forthcoming potential changes that may be applied to the Operational Qualification of dissolution instruments. These changes are a hotbed of discussion at the moment of going to press (ref. 6), but these issues need to be investigated and acted upon, not so much to conform to any new rules that may arise, but because we must strive to produce an instrument which not only passes any test that is currently, or may be, required but also for the ease of the operator who has to use the instrument on a daily basis.

Main advantages of the Dissolution Testers with implemented critical design features. The main advantages are outlined below:

#### Pump and Heater Installation

The heating of the water bath section in a dissolution tester is normally the last point on the development list for most instrument manufacturers. This is generally limited to a “me too” type of heated circulator, which sits on the workbench just beside the dissolution tester. Most of these heated circulators have one control sensor with a fixed mounted pump mechanism.

The first issue is the safety of the heating system and with Pharma Test units there is a safety sensor as well as a control sensor. The second issue is the accessibility and construction of the heating elements which coincidentally contains the circulation pump. The heating system is shown below in figure 1. It is conveniently accessed via a small drawer unit without having to disturb the positioning of the bath itself. It also contains a safety sensor after the heating element as well as a safety over-temperature switch and a thermal fuse, items missing in several current designs. The built-in vibration suppression is illustrated below:



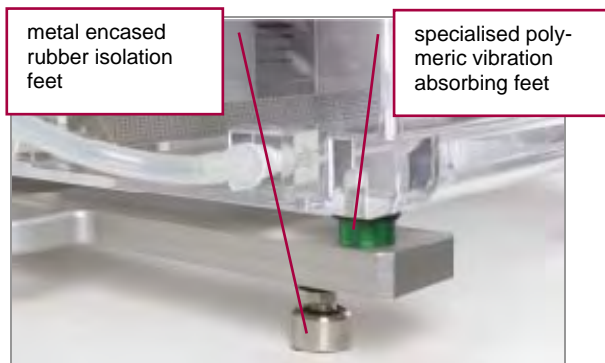
sprung support platform to eliminate any vibration from the pump

quick disconnects for rapid access to water bath connections

You can see that the pump is suspended on a sprung platform and this eliminates virtually all potential vibration sources from the pumped heating system. Compare this with bench mounted heater/circulators.

### The Water Bath Installation

The water bath is also set up for vibration damping. This design has also taken into account the impact of environmental vibration sources such as fridges, pumps, A/C systems and the like which are an intrinsic part of modern laboratory installations. The vibration damping is clearly shown below:



metal encased rubber isolation feet

specialised polymeric vibration absorbing feet

You will note from the figure above that the first line of defence against environmental vibration is the installation of metal encapsulated rubber feet. This mechanically “decouples” the dissolution tester from the work bench. These feet also allow the easy levelling of the dissolution tester prior to installation.

The second line of defence is the installation of unique, specialised polymeric vibration dampers (Vibroban™) purely for the water bath isolation from the rest of the dissolution tester. This effectively provides a second decoupling mechanism to insure that almost all vibration emanating from the working environment is eliminated. The effects of this system in the face of external environmental vibration sources can be seen below. The results clearly show the huge influence of vibration while doing a Prednisone dissolution test.

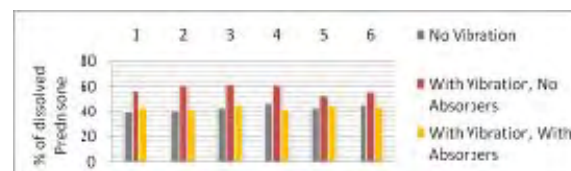
### The Effect of Environmental Vibration Sources

Vessel	a) No Vibration	b) Without Absorbers	c) With Absorbers
1	40.11	56.90	43.51
2	41.95	61.15	42.30
3	43.45	62.07	45.98
4	46.90	61.38	42.41
5	43.68	53.22	45.40
6	45.98	55.98	44.60
mean	43.68	58.45	44.87

a) no vibration

b) with vibration (0.5 µm) and instrument without vibration absorbers

c) with vibration (0.5 µm) and instrument with vibration absorbers



Certainly compared to the results shown above, the effects of vibration in most available instruments compared to instruments which contain these critical features are certainly important enough to take into account when choosing a new Dissolution Tester.

### Conclusions

Many problems can arise within the laboratory environment to detrimentally influence the dissolution process. Some of these issues such as de-aeration of the dissolution medium can be effectively handled with modern medium preparation instruments which are widely available.

Issues such as vibration, both intrinsic and environmental have different effects on different makes of instrument. It has been illustrated on more than one occasion that “thinking outside the box” and implementing some critical features based on intensive R&D offers a multi directional approach to eliminating factors which are detrimental to the whole dissolution process and not just certain aspects therein. In this way users can be offered an unrivalled degree of security in the dissolution process which not only meet current requirements, but will afford an additional buffer so as to be prepared for proposed norms which are currently under discussion.

## Presenting the Expanded PHARMAG Pilot Plant Range of Products



The PHARMAG Pilot Plant system is designed for specialist applications such as development of new products, scaling up from test to small batch quantities and the production of speciality materials that are not necessarily manufactured in large quantities. It is equally suited to the fine chemical and cosmetical environment as well as the pharmaceutical industry. The PHARMAG range also finds broad application in pharmacy teaching departments (universities) and in the manufacture of low volume, speciality pharmacist products. The basis of the system is the UAM power plant which employs an industry standardised flange system to connect various interchangeable attachments of different applications.

These attachments include mixers, stirrers, granulators, liquid and ointment fillers, and product enhancing tools such as coating pans, pelletizers, and more. A single punch eccentric and a rotary Karnavati tablet press as well as a small scale Karnavati capsule filler complete the range. Since the UAM has an industry standardised tool attachment flange, you can benefit from its power and stability by attaching any of your existing tools from other manufacturers.



You can also use the PHARMAG range of high quality accessories and tools by attaching them your existing motor drives by virtue of the same universal flange system. The PHARMAG Pilot Plant system, with UAM power plant and accessories, provides a top quality solution to small batch production at a reasonable cost.

### New Additions for 2008

As of the start of this year, we have significantly enlarged our PHARMA Pilot Plant product range. Now available are high speed powder mixers, stainless steel ball mills, planetary agitators, suppository filling apparatus and many more other attachable accessories.

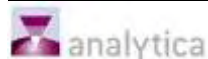


We also now offer a rotary tablet press which is available in 3 different versions: Mini Press IIB (standard version B tooling, 10 positions), Mini Press IID (standard version D tooling, 8 positions) and Mini Press IIS (sense force instrumentation). The maximum output is 27,600 tablets per hour.

Furthermore we added a fully automated capsule filling machine to our product portfolio. The MiniCap is designed for R&D and small scale manufacturing. It is an automatic bench-top capsule filling machine for powder and pellet filling which can also handle mini compact sizes and is able to produce up to 3,000 capsules per hour.



To learn more about the PHARMAG Pilot Plant system, visit the website [www.pharmag.de](http://www.pharmag.de) or contact us and ask for our brochure.



## Exhibition Forecast: Analytica 2008, Munich

### PTB 320

At Analytica 2008 we will present for the first time the new PTB 320 automated "selectable mode" tablet hardness test instrument. The PTB 320 is used to measure the thickness (height), the diameter (length) and hardness of tablets, caplets, oblong shaped samples, seeds, and other solid samples. The LCD display guides the user through editing all product-descriptive data, activating or de-activating the individual testing stations. The system furthermore can file up to 20 test methods. These include nominal data for each station, as well as product descriptive information.

In order to meet forthcoming requirements of pharmacopoeias worldwide the PTB 320 offers qualification and calibration procedures for all stations, printed calibration and qualification reports, selectable testing modes for the hardness test which use either linear force or linear speed increase rates. Calibration and qualification is performed by using reference standards.

The unique sample positioning device inside the testing stations allows the measurement of the sample's thickness and after that its diameter, without touching or moving the tablet. A laser station (Class 1M) measures the thickness while the stepper motor driven hardness station is used to measure the diameter followed by the hardness, which is in turn measured by the built-in load-cell (strain gauge).

The test results are displayed on the LCD display and may be printed out either by the optional built-in printer or alternatively on an external printer. Every PTB 320 instrument is equipped with a Bluetooth™ wireless interface. This can be used to conveniently transmit data and to establish a wireless connection to a computer.

### PTG-S3 NIR

The automated powder characterisation system PTG-S3 can now be equipped with a fibre optic optimized NIR detector for additional analysis of:

- Moisture content of the tested product
- API concentration
- Blend homogeneity of all components

In terms of pharmaceutical applications, NIR Measurement has been useful to understand the distribution of an API within an excipient matrix but with the full compliment of NIR spectral data it is possible to also determine the chemical images for each excipient.

With knowledge of all components within a pharmaceutical formulation, NIR measurement can serve to determine the blend homogeneity of all components, not only the API. Exposing the micro-scale interactions of a sample may also be a useful method to understand process variation, and how it affects product performance. The PTG-S3 NIR can then become a viable method for pharmaceutical process control.



The picture above also shows the optionally available dust protection cover for the PTG-S3. This cover includes a connector for a vacuum de-duster and a vacuum adjustment slider.

### IDS 500

The new fibre optic application IDS 500 for dissolution testing gives the user the possibility to connect a standard dissolution tester to a fibre-optic based spectrophotometer to perform precise and fast In Situ measurements. The fibre optic probes are connected directly to the spectrophotometer. The In Situ measurement takes place between shaft and the vessel-wall, min. 1cm away from the wall. It surpasses the current requirements as listed in the current USP and EP. The System is powered by the user friendly, fully 21 CFR Part 11 compliant ARGUS Software.

The IDS 500 System from PHARMA TEST is unique in many ways and brings a new dimension to dissolution measurements. For example, the DAD (Carl Zeiss) is optimised for fibre optic measurement. The fibre optics are made using solarisation resistant material, so they



are much more resistant to UV-radiation and have a much longer life time. This system has only one diode array spectrophotometer and yet is still able to operate with 8 separate fibre optic sensor paths which are multiplexed to a central sampling unit. An ultra-fast precise 8 cell changer is also integrated into the spectrophotometer.

In respect to maintenance and service all components are easily accessible. It guarantees to satisfy even the highest demands for robustness and reliability. The use of fibre optic light transmission inside the IDS 500 allows an optical system design without moving parts. A fibre optic beam coupler eliminates the requirement for a mirror switching at the light source (change from  $D_2$  to Tungsten lamp) as to be found in conventional spectrometers. The overall result is improved reliability and long term system stability.

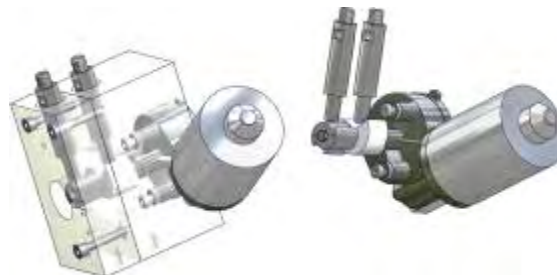
The custom-built fibre optic technology used in the SA 500 is combined with a unique diode array detection module to form a unit which features very low energy loss compared to conventional optical systems. These higher energy levels permit a more rapid scanning of the array in comparison to what is found in more conventional detectors resulting in a much faster scanning capability for a given signal to noise ratio.

The data analysis is performed by the fully 21 CFR Part 11 compliant ARGUS Software. This software was developed and designed to meet the operational, as well as the conformity needs of our customers. Thanks to its user-friendly wizards and toolkit help system, the ARGUS Software is not only secure and regulation-compliant, but is also as easy to use as standard office software.

Turbidity is no problem. With the DAD Spectrometer it is possible to perform turbidity compensation using an unaffected (non-absorbing) wavelength region (for example: 400 - 600nm). Also, multi-component analysis is offered as a standard feature and will often eliminate the need of a HPLC system. In short, the IDS 500 system provides a complete spectrophotometric solution for dissolution testing, which not only offers a robust hardware package, but also features a DAD spectrometer optimized for fibre optic measurement with an 8 channel cell changer. On top of all that comes a secure, industry compliant and user-friendly software package.

### PT-TD2 (EP/USP) Norm

The latest version of our well established tap density tester PT-TD1 is now compliant to both the EP and the USP pharmacopoeias. Previously, customers had to specify in compliance to which pharmacopeia they would like the instruments to work and we would have manufactured the gear mechanism accordingly.



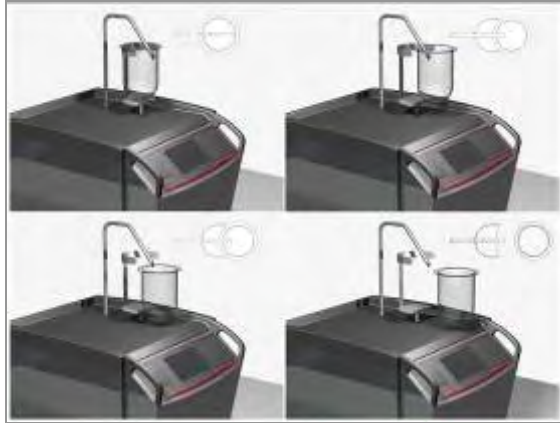
Thanks to this redesign of the gear mechanism as shown above, all PT-TD2 instruments can now work according to both pharmacopoeias at any point of time.

### DDS 4 Facelift and Redesigned Filling Station

The popular media preparation system DDS 4 has been given a facelift. Not only does this improve the instrument's visual appeal, it also enhances its ease of use.



The added handholds improve the ease of moving the instrument. Furthermore, the newly designed filling station makes it more convenient to take a filled vessel out of the filling station. With this ingenious "half-moon" shaped design of the filling station's base, it is now possible to remove the vessel without tilting it. You can see this illustrated in the sequence of pictures below:



**PT-LT**

The new PT-LT leak test apparatus is an elegant solution to evaluate the quality of the packaging and the sealing perfection of packed strips, blisters and small sachets containing tablets or liquids.



The instrument's height remains unchanged so that it continues to fit easily under a standard lab work bench.

**PHARMA TEST Both Occupancy for Analytica 2008**

<b>Day 1:</b> Tuesday the 1 <sup>st</sup> of April 2008:	Dr. D. Beilke, Dr. J. Burmicz, Mr. B. Fähler, Dr. H. Kurt
<b>Day 2:</b> Wednesday the 2 <sup>nd</sup> of April 2008:	Dr. D. Beilke, Dr. J. Burmicz, Mr. B. Fähler, Dr. H. Kurt
<b>Day 3:</b> Thursday the 3 <sup>rd</sup> of April 2008:	Dr. D. Beilke, Dr. J. Burmicz, Mr. B. Fähler, Mr. F. Fähler, Mrs. P. Fähler, Mrs. V. Gamez-Hacker, Dr. H. Kurt
<b>Day 4:</b> Friday the 4 <sup>th</sup> of April 2008:	Dr. D. Beilke, Mr. B. Fähler, Mr. F. Fähler, Mrs. P. Fähler, Mrs. V. Gamez-Hacker, Dr. H. Kurt

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