

Local Solutions for the Global Pharmaceutical Industry

▶ TPW3 and APW3 perform fully automated sample preparation and analysis for the most common pharmaceutical tests in the Development and Quality Assurance functions. Starting as early as Phase 1 Development, all the way through to Manufacturing Quality Assurance, Zymark® Assay Workstations will increase laboratory productivity and analytical quality. TPW3 and APW3 are compatible with SQL Server Enterprise Edition. This allows electronically approved methods to be made available for the local use in:

- | | | |
|-----------------------------|---------------------------------|------------------------|
| ▶ Method Development | ▶ Process Validation | ▶ Raw Material Testing |
| ▶ Material Characterization | ▶ Product Transfer | ▶ QA Release Testing |
| ▶ Formulation Development | ▶ Equipment Cleaning Validation | ▶ On Going Stability |

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TPW3 | APW3 Assay Workstations



TPW3 and APW3 are third generation products that have improved productivity for over 15 years. They perform fully automated sample preparation and analysis for the most common pharmaceutical tests in the Development and Quality Assurance laboratories.

The **TPW3** is specifically designed to prepare and analyze pharmaceutical solid dosage forms and intermediate granulations. The TPW3 uses a high shear homogenizer to disperse samples in a vessel containing 20–100 mL or 50–500 mL of solvent. This makes TPW ideal to efficiently extract analyte for:

- ▶ Tablet and Capsule Stability Indicating Assays
- ▶ Tablet and Capsule Content Uniformity
- ▶ Blend and Granulation Uniformity



The **APW3** is intended for use testing pure Active Pharmaceutical Ingredients (APIs). It may be used in other situations where smaller solvent volume is required. The APW3 processes samples in 16 mm x 100 mm tubes. The APW3 may be used for diverse applications, including:

- ▶ API assay
- ▶ API stability and other impurities
- ▶ Residual components
- ▶ Cleaning validation
- ▶ Creams and semi-solid dosage forms
- ▶ Drug loaded medical devices
- ▶ Other extractions for assay



Customer Collaboration

Zymark® experts have worked with the pharmaceutical industry's expert automation chemists to design and test these products. This three year long collaboration has resulted in products that maintain the basic functionality of the well-known TPW II and Prelude products while increasing:

- ▶ Method flexibility
- ▶ Analytical quality
- ▶ Capacity
- ▶ Reliability
- ▶ Productivity





Improved Quality of Analysis

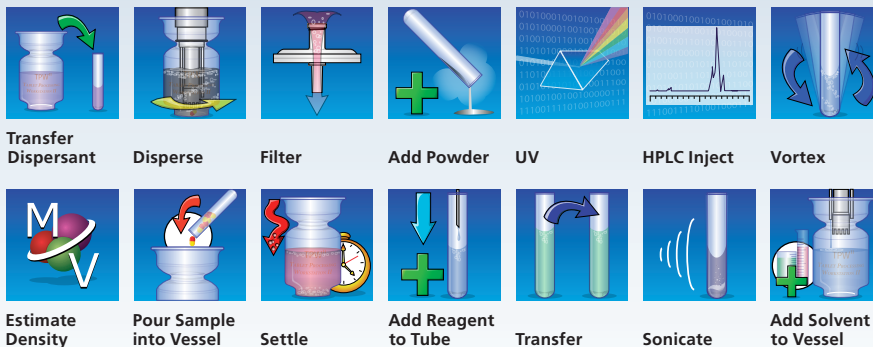
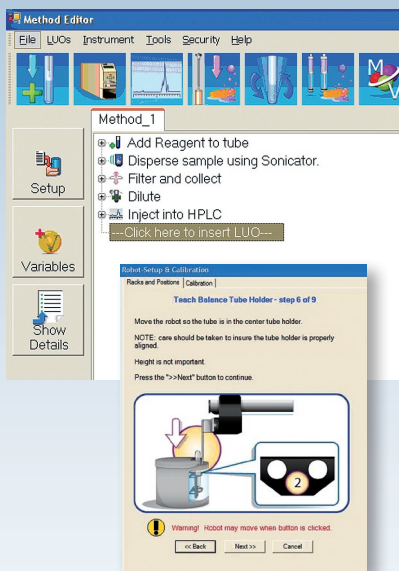
The TPW3 and APW3 improve the quality for every day laboratory tasks as well as more complicated sample preparations. For walk-up use of just a few samples, or extended runs of many samples, you can be confident in the quality of your analytical results.

- ▶ Gravimetric confirmation assures liquid dispense accuracy and precision
- ▶ Allows true analytical transfer
- ▶ Eliminates analyst technique as a source of variability
- ▶ Serial processing assures the timing of method steps and wait time for injection are identical from sample to sample
- ▶ Assays unstable drugs and degradents immediately after preparation
- ▶ Provides a level of precision that is difficult to achieve in a batch mode of operation
- ▶ Technique dependent steps such as dispersing or extracting are precisely defined and controlled to be reproducible
- ▶ In most cases, optimized methods will meet or exceed manually obtained analyte recovery
- ▶ Correlation coefficients are expected to meet or exceed manual results

Ease of Use

Methods are easily written by selecting icons that represent various method steps. Each step includes commonly used default values with easy “fill in the blank” operation for each parameter:

- ▶ Software recommends settings for dilutions and other parameters
- ▶ Key method variables can be applied at run time to evaluate their impact in method development
- ▶ Database sharing makes it easy to use the exact same method throughout the global organization



Increased Productivity

Productivity brought by the TPW3 and APW3 Workstation transcends typical cost of labor considerations.

- ▶ The saved labor allows more time for other, more critical, challenges
- ▶ Typically a TPW3 can do the work of two analysts
- ▶ When applied early in development, benefits will compound throughout the product's life cycle
- ▶ Waters Empower 2 interface provides complete turnkey operation
- ▶ APW3 and TPW3 have been designed with reliability in mind
- ▶ Easy to teach positioning requires less time for support
- ▶ The secure audit trail provides a faster and more accurate investigation of Out Of Specification (OOS) events
- ▶ Increased productivity allows more samples to be run, which translates to a more robust process validation design
- ▶ Compact benchtop design fits into most any laboratories
- ▶ Network capabilities allows adding more units to easily expand capacity

Fully Compliant

The TPW3 and APW3 are primarily intended for use within the regulated pharmaceutical industry around the world. Compliance has been taking into consideration in all aspects of use.

- ▶ The FDA and other regulatory agencies around the world routinely accept Zymark® Assay Workstations
- ▶ The TPW3 and APW3 Workstations use the same chemistry already validated using standard laboratory techniques
- ▶ Re-validation of the original chemistry is typically not required
- ▶ The FDA has accepted submissions originally developed on the Processing Workstations
- ▶ Comprehensive and secure documentation provides 21 CFR Part 11 compliance
- ▶ Electronic signatures serve to record the approval status of methods and test results
- ▶ Adapted methods are usually filed as an Alternate Method in annual NDA and ANDA updates
- ▶ Dispensed volumes comply with USP requirements for volumetric delivery
- ▶ TPW3 and APW3 do not use unproven, inferential, chemo-metric approaches
- ▶ Demonstration of equivalent recovery and minimal carry over is typically used to demonstrate suitability
- ▶ A full line of validation services are available from SOTAX services
- ▶ Organic, aqueous and mixed waste streams are built in and standard

Increase Capabilities with Optional Accessories

Options expand the basic capability to meet individual customer needs.

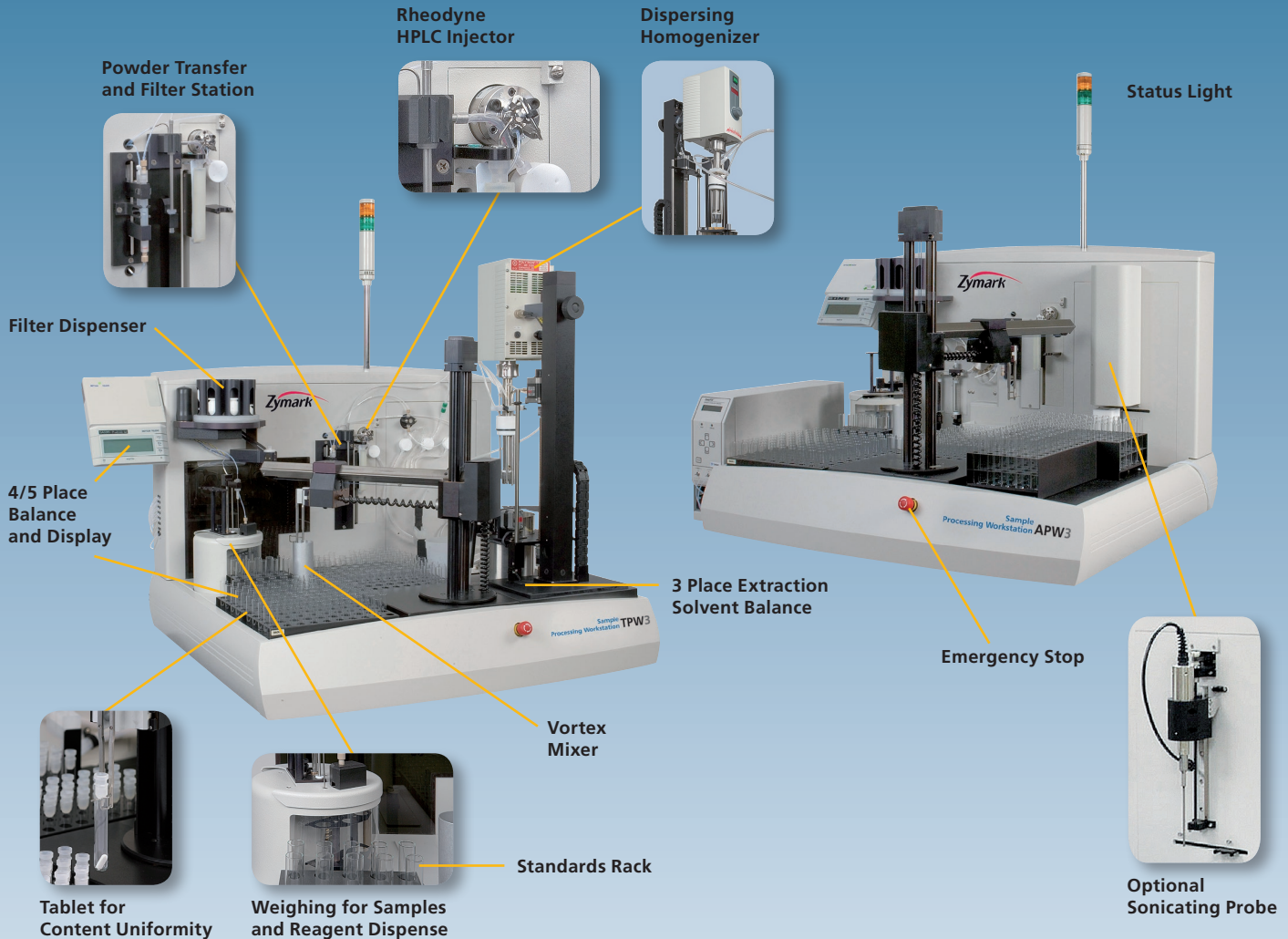
- ▶ EasyFill sample collection stores samples in septum-capped vials and 96 well plates
- ▶ Sonicating probe and wash station facilitates preparing solutions. It automatically reads preparation temperature
- ▶ Bar code reader supports common industry formats
- ▶ SOTAX and Zymark® certified Pall™ PSF filters and common brand 25 mm luer-lock filters
- ▶ Acid resistant versions of the TPW3 and APW3
- ▶ Rack adapter for TurboVap LV allows convenient transport for rapid evaporation
- ▶ Large tube adapter provides utility for 20 x 150 mm sample tubes for TPW3
- ▶ Low dose homogenizer allows dispersions to be performed at 20–100 mL
- ▶ Evaporation resistant caps



Attributes

APW3 TPW3

- ▶ ▶ **Capacity and Flexibility**
- ▶ ▶ Up to 300 samples can run unattended using single tube methods
- ▶ ▶ 150 single step dilutions can be performed
- ▶ ▶ Up to 100 samples can run unattended using a single step dilution
- ▶ ▶ Depending upon method settings, a very large number of methods may be linked together
- ▶ ▶ Depending upon method settings, a very large number of methods may be overlapped
- ▶ ▶ Up to nine solvents or reagents are available
- ▶ ▶ Up to five solvents or reagents are available
- ▶ ▶ Abbreviated methods may be used to evaluate functionality
- ▶ ▶ Variables can be easily modified for method developers
- ▶ ▶ **Dispersions and Extraction**
- ▶ ▶ Disperses samples in vessel with volumes from 20–100 mL and 50–500mL
- ▶ ▶ High shear homogenizer for fast dispersion and extraction
- ▶ ▶ Disperses samples in test tubes with volumes from 0.5–10 mL in 16 x 100 mm tubes
- ▶ ▶ Redesigned optional sonicating probe to facilitate rapid solubility or extraction
- ▶ ▶ Infrared temperature measurement for optional sonicating probe
- ▶ ▶ Filter dispersion with a wide variety of pall automation certified filters
- ▶ ▶ Mixing with reciprocating vortexer
- ▶ ▶ **Weighing**
- ▶ ▶ Gravimetric confirmation assures dispenses meet USP and ASTM requirements for volumetric measurement
- ▶ ▶ Utilizes a dual range four to five-place balance to weigh samples, add reagents and carry out dilutions
- ▶ ▶ Uses a three place balance to weigh dispersant solvent for high shear mixing
- ▶ ▶ Gravimetric assist dispensing may be de-selected to allow for faster operation when accuracy is less critical
- ▶ ▶ Gravimetric traceability throughout the sample prep provides a record for OOS investigations and assurance of sample integrity
- ▶ ▶ **Dilution**
- ▶ ▶ Dilutions ratios as high as 1:10,000 can be performed
- ▶ ▶ Dilution step details are automatically suggested
- ▶ ▶ Two single step dilutions can be performed within a method
- ▶ ▶ Overlapping methods allows serial dilutions to be performed
- ▶ ▶ **Finish**
- ▶ ▶ HPLC injection is enabled with an onboard rheodyne injector
- ▶ ▶ Integrated interface for Waters Empower 2
- ▶ ▶ Versatile control of standards for bracketing
- ▶ ▶ Multiple injections may be performed within a method
- ▶ ▶ On-line UV/VIS detection via contact closure
- ▶ ▶ Samples may be collected in a variety of formats for off line analysis
- ▶ ▶ Flexible cleaning capabilities
- ▶ ▶ **Software**
- ▶ ▶ Provided with SQL Server Express Edition
- ▶ ▶ SQL Enterprise Edition database compatible
- ▶ ▶ Optional factory installed SQL Server Workgroup Edition
- ▶ ▶ 21 CFR 11 compliant
- ▶ ▶ Easy to use step by step LUO (laboratory unit operation)
- ▶ ▶ Software makes all variables available for complete control
- ▶ ▶ Security is customer it configurable to meet your corporate policy
- ▶ ▶ Customer IT Configurable for LIMS
- ▶ ▶ XML, Excel, PDF output supported
- ▶ ▶ Diagnostics are captured in the compliant database
- ▶ ▶ Fault tolerant networking to shared SQL database
- ▶ ▶ **Hardware**
- ▶ ▶ All new control architecture for supportability and reliability
- ▶ ▶ Positive encoder feedback for precise device control
- ▶ ▶ Multipoint position referencing
- ▶ ▶ Position and click teaching



Customer Services & Support

The SOTAX services is equipped to provide our TPW3 and APW3 customers with a variety of support options:

- ▶ Flexible service plans on standardized and/or customized Preventive Maintenance to keep your equipment running trouble-free
- ▶ Technical Support via phone, fax or email
- ▶ Introductory, advanced and troubleshooting training courses to enhance your product experience
- ▶ On site Application Services to maximize the return on your automation investment
- ▶ Support for Method Setup, Development and Transfer from manual to automation
- ▶ System and Software Qualification of your equipments as of Installation IQ & Operational Qualification to Re-Qualification on regular basis (3, 6 and 12 Months) including all required cGLP/cGMP Documentation
- ▶ Re-Installation after any move at any new location with full Re-Qualification
- ▶ On site Repairs after breakdown with 24/48/72 hours response time
- ▶ Upgrades and Updates of installed systems and customized modifications

To request more information on our services and support: services@sotax.com