# WinSOTAX Tablet Dissolution Software

## Our design fits everywhere

SWISS QUALITY
ISO 9001

## The advanced dissolution software

WinSOTAX was introduced in 1998 and was developed under consideration of the latest regulations including GAMP, GALP and complies with 21 CFR Part 11. New considerations from customers regarding 21 CFR Part 11 are regularly implemented. SOTAX maintains a quality system that received the ISO 9001 certification in 1996 and extended in 1999 to the TickIT quality system for software development.


sotax

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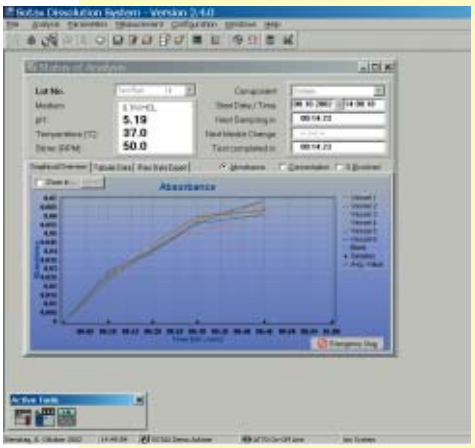
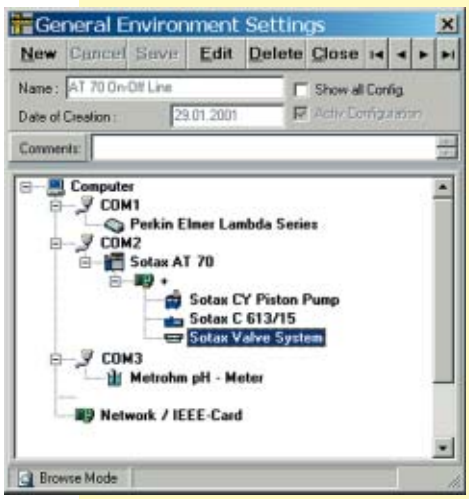
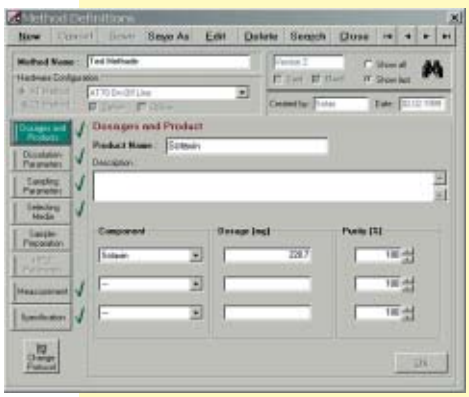


*Test run*




*Device configuration*



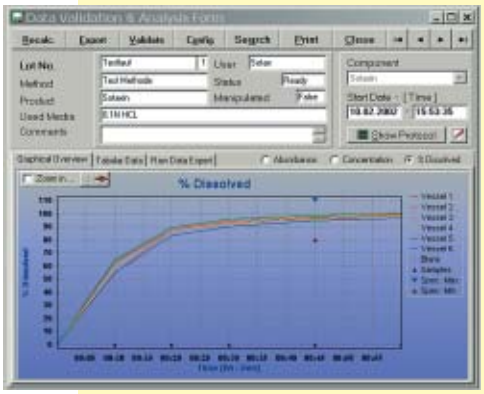
*Method screen*

## WinSOTAX is an integrated software package for all SOTAX dissolution systems including:

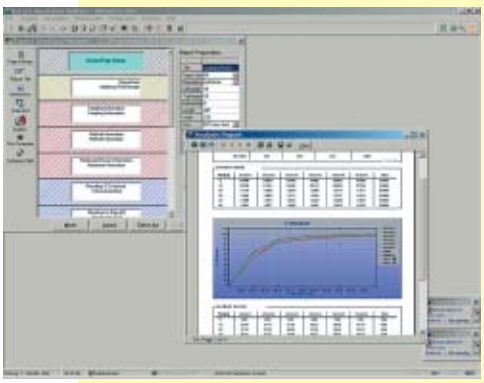
- Semi-automated Off-line
- Semi-automated On-line
- HPLC On-line
- Fully automated systems AT 70*smart* and BS 60 Basket Station
- Flow-through system (USP 4)

## Main features

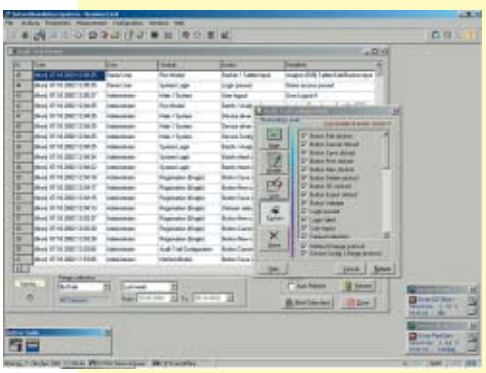
- High speed 32 Bit design for Windows 98/NT/2000/XP
- User friendly as users see only menus and dialogs that conform to their hardware configuration and user rights
- Controls rpm, temperature, pumps and fraction collector
- Menus include:
  - Hardware Selection Menu
  - Method Generator
  - Report Generator to create custom report formats with tabular and graphics of rpm, temperature and pH including statistical functions as min./max., mean and standard deviation
- Test execution Windows with real time display of tabular data or graphics and status monitors for devices
- Log file for all parameters with real time protocol
- Excipient (placebo) or impurity subtraction
- Single and multi-component analysis
- Export functions of calculated data into Excel or reports in Word format
- Context based on-line help system



*View data*



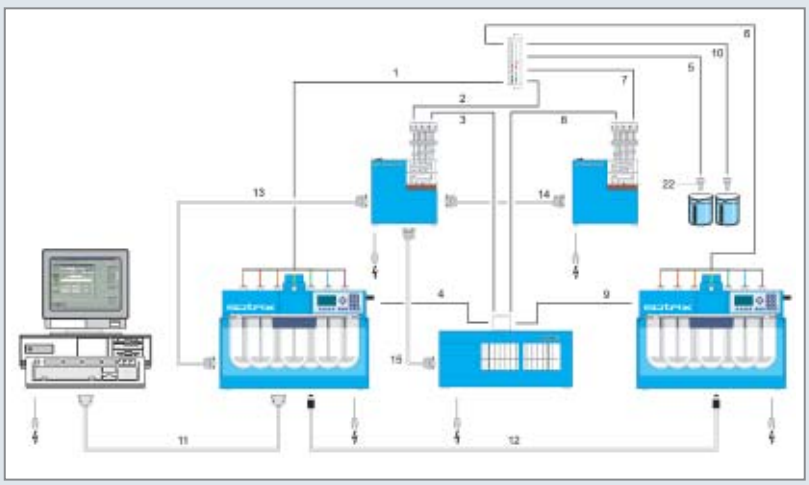
*Report*



*Audit trail*

## Available Optional Drivers

- UV on-line drivers for the most common spectrophotometers (Perkin Elmer, Agilent 8453, Shimadzu, Beckman, Unicam, Biotek) with calculation of concentration and percentage dissolved including statistical functions
- Batch processing module to control SOTAX AT 70*smart* and BS 60 Basket Station allows the user to perform up to 15 paddle or 10 basket tests
- Interface for pH measurements and protocolling
- Standard monitoring with different calculation methods including bracketing
- Virtual dilution with 16 position cell changers utilizing two sets of cuvettes, e.g. dilution 1:10 with 10mm and 1mm pathlength
- Cell Grouping: Grouping of test vessels (e.g. comparison of 2 different sample batches in each of 3 vessels with different test conditions)
- HPLC on-line with control of sample collection and injection in combination with an Agilent 1100, Thermo or Shimadzu HPLC systems including HPLC software
- Manual data input of spectrophotometric or HPLC data with calculation of concentration and percent dissolved
- Control of double on-line or off-line systems



*SOTAX AT 7smart double off-line automated system for dissolution test according to USP with solvent replacement*

## WinSOTAX Validation

WinSOTAX was developed and structurally validated following a Certified Quality System, which conforms to GMP and ISO 9001 requirements. A Standard Development Life Cycle has been followed which conforms to ISO 9001 Standard. The output of this Life Cycle includes the following documents:

- The Product Description
- The Software Quality Plan
- The Functional Specification
- The Test Plan
- The Test Procures and Test Data
- The Software Release Notice and Revision Control
- The Source Code Documentation

The existence of these documents and the procedure used in their production are formal requirements of the SOTAX Quality System. The integrity of this SOTAX Quality System is routinely audited.

These documents are available for review on site and will require a nondisclosure agreement to be provided by those wanting access to the information.

SOFTWARE STRUCTURAL
VALIDATION CERTIFICATE
(GMP / ISO 9001)

This Product was developed and structurally validated following a Certified Quality System which conforms to GMP and ISO 9001 requirements.
Further it fulfills the requirements of the rules and regulations 21 CRF Part 11 – Electronic Records; Electronic Signatures; Final Rule from the FDA department of Health and Human services, dated on March 20, 1997.
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**Software Product:**

SOTAX WinSOTAX Revision 2D (2.3.1)

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sotax

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*Software structural validation certificate*

## 21 CFR Part 11 compliance

It fulfils the requirements of the rules and regulations of 21 CRF Part 11 – Electronic Records; Electronic Signatures; Final Rule from the FDA department of Health and Human services, dated on March 20, 1997.

- Fully 21 CFR Part 11 compliant
- High security through closed system with password access and different user rights assignable. Periodic password changes and user lock out after failed log on selectable.
- Raw data maintained for verification at any time, original methods saved and method changes are recorded as a new version with time/date stamps
- Complete audit trail for access, tests, method and hardware changes
- Electronic signature for report review, release or rejection

### Hardware Configuration

- min. Pentium III
- min. 64 MB RAM
- CD-ROM drive
- min. 800x600 resolution, 1024x768 recommended

For further information and inquiries about the software, please don't hesitate to contact us.

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