



On-line



Off-line

On-line

The SOTAX CE 7smart can be coupled with a UV-visible spectrophotometer. On-line measurements can be made throughout the dissolution. The CE 7smart and the UV-visible spectrophotometer are controlled using WinSOTAX Advanced Dissolution Software. WinSOTAX has interfaces for numerous UV's such as the Agilent 8453, Beckman, Perkin Elmer, Shimadzu, Thermo etc.

Off-line

For off-line analysis, the SOTAX CE 7smart can be connected to a fraction collector. Off-line fraction collection is available for both open & closed systems. When utilizing the SOTAX CP 7 positive displacement pump, samples can be accurately withdrawn from 1.5 ml and up. With either the SOTAX C613/C615 fraction collectors you can sample into presealed HPLC vials of any size for HPLC.

On-/Off-line

When maximum flexibility is needed the SOTAX CE 7smart can be connected to both a UV and a fraction collector. Both additions can be used alone or together.

WinSOTAX Advanced Dissolution Software

WinSOTAX was the first commercially available Dissolution Software package provided by any dissolution manufacturer. First introduced in 1998, WinSOTAX was developed under the latest regulations including GAMP, GALP, ISO 9001 software standards and completely complies with the rules and regulations of 21 CFR Part 11 set out by the FDA. It has evolved over the past years 5 years under new considerations and guidelines issued recently by the FDA regarding 21 CFR Part 11. The integrity of WinSOTAX is routinely audited by the SOTAX Quality System. SOTAX has also been successfully audited by numerous pharmaceutical companies worldwide.

WinSOTAX is an integrated Dissolution Software package that controls the CE 7smart and its many systems in open or closed loop configurations including:

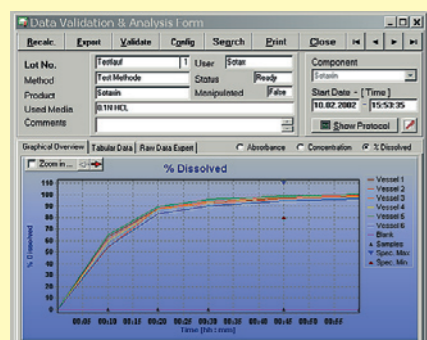
- automated OFF-line with fraction collector
- automated ON-line with spectrophotometer
- automated ON-off line with spectrophotometer and fraction collector
- automated ON-line HPLC
- automated media changes
- automated cleaning functions

WinSOTAX is also essential in the calculations involved in open and closed loop configurations. For closed loop systems, WinSOTAX calculates % dissolved much like USP 1 and 2 using a fixed volume. However, in open loop configurations, % dissolved is calculated differently where the measurable active at a particular time point is proportional to a particular volume that has passed through the cell. Using simple calculus, WinSOTAX automatically converts the % dissolved data into that which is comparable to USP 1 or 2. Other important features include:

- User-friendly method set up, results reporting, hardware control
- Real time data collection in % dissolved, abs or concentration
- Single or multi-component analysis
- Placebo or impurity subtraction
- Flow rate and temperature reporting
- Control of UV (different drivers available), sampling time points, sample injections and sample volume collections

Another important feature of WinSOTAX is the cell-grouping feature which allows the collection of data by grouping different cells with different testing conditions (e.g. different flow rates, different dose etc.). It is another essential research tool for use with the CE 7smart USP 4 "flow-through" method.

WinSOTAX operates and has been validated on Windows 2000/XP and requires a minimum Pentium III. It is fully networkable and LIMS compatible. When installed, WinSOTAX is supplied with a complete validation package and supported by SOTAX Certified Software Engineers worldwide.



WinSOTAX

CE7
Smart

CE 7smart USP 4 "Flow-Through" Dissolution Systems

SWISS
QUALITY
ISO 9001

Our design fits everywhere



- Dissolution testing of tablets, capsules, implants, suspensions, drug-eluting stents, ointments, creams, microspheres
- Analysis on-line with UV-VIS
- Off-line fraction collection
- Limitless volume option from 15 ml → ∞ (USP approved for all volumes)
- Open or closed loop configurations
- Media selector allows for easy pH changes
- Integrated cleaning functions
- Controlled by 21 CFR Part 11 compliant WinSOTAX Advanced Dissolution Software

USP 4
The most versatile dissolution system in the world!

sotax

sotax



CE 7smart cell



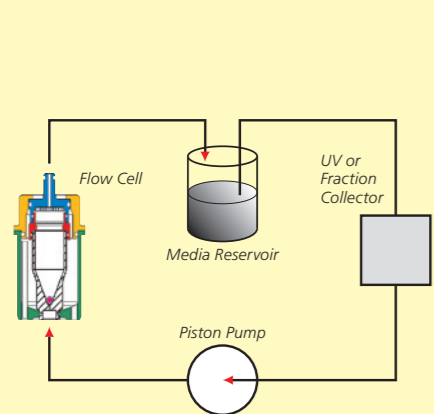
Cell block

Dissolution tests according to the "flow-through" method (USP 4)

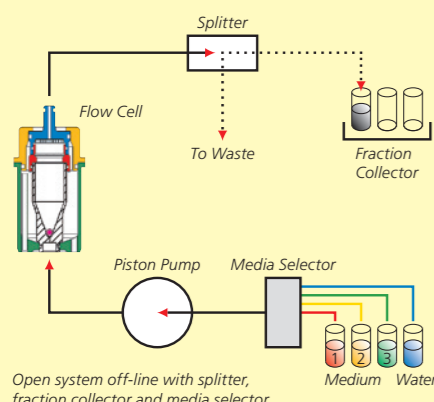
In the "flow-through" method (USP apparatus 4) the test sample is located in a small volume cell through which solvent passes at a temperature of 37 °C. The eluate is filtered upon leaving the cell and then can be analyzed directly or collected in fractions. The most important method parameters are cell type and "flow-through" rate. The "flow-through" method permits constant optimal sink conditions due to the continuous flow of fresh solvent, rapid pH-changes and continuous sampling. As a result, the tests show an improved in-vitro/in-vivo correlation. With the "flow-through" method there is no restriction in solvent volume. This means that the influence of poor sink conditions on the test can be avoided altogether by using larger volumes of solvent. The "flow-through" method is particularly recommended for poorly soluble products and modified release forms, needing a large amount of volume, as opposed to the restricted possibilities of the USP stirrer methods.

Multiple sample cell types

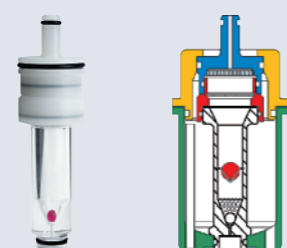
The SOTAX CE 7smart is capable of employing the "flow-through" method USP 4 for many different dosage forms. Traditional dosage forms such as tablets and capsules can be tested using the same system as implants, stents, suppositories and powder or granulates. Six (6) cell types are available to accommodate most dosage forms.



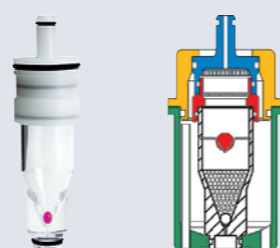
Closed system with UV on-line or with fraction collector



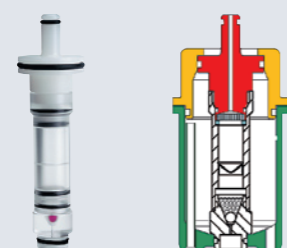
Open system off-line with splitter, fraction collector and media selector



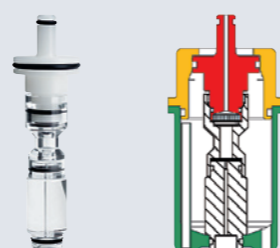
Tablet cell 12 mm



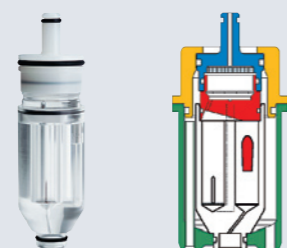
Tablet cell 22.6 mm



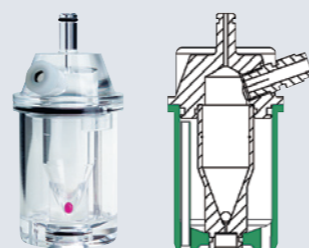
Cell for powders and granulates



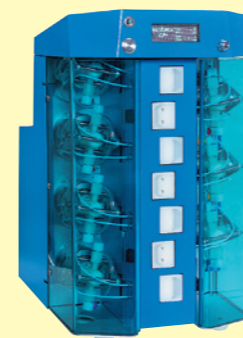
Cell for implants



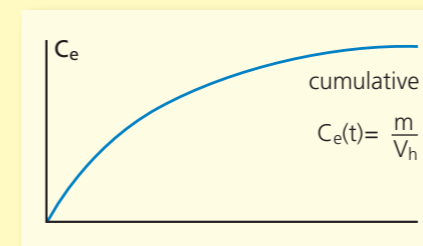
Cell for suppositories and soft gelatin capsules



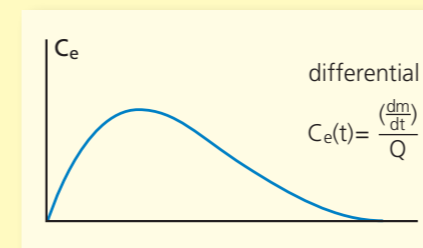
Temperature-measuring head



SOTAX CP 7 Ceramic Piston Pump



USP stirring methods (apparatus 1+2)



USP "flow-through" method (apparatus 4)



Closed system big volumes



Closed system small volumes

The importance of the pump

In a "flow-through" dissolution method, the pump is responsible for ensuring the most important parameter: the flow rate of the media. This flow rate must stay constant throughout the duration of the test, even in cases of back pressure created by filter resistance. The USP regulations require a sinusoidal flow profile with a pulse action of 120 +/- 10 pulses per minute.

SOTAX highly recommends the use of the SOTAX CP 7 Piston Pump, which has been specially developed for the USP 4 "flow-through" dissolution method. This pump is equipped with 7 valveless ceramic pump heads, insuring a very high level of reproducibility and consistency for the flow rate. This pump also fulfills another USP requirement which is to only use inert material (ceramic). Moreover, the maintenance of such a pump is considerably reduced due to the use of these valveless ceramic pump heads.

The flow rate can be adjusted from 1.5 to 35 ml/min, fulfilling the USP standard flow rate recommendations of 4, 8 and 16 ml/min. The flow rate can also be automatically adjusted through the use of the WinSOTAX software (no need for manual adjustment). The most important parameter of this pump is the fact that the flow rate can be adjusted channel per channel. This feature is advantageous during the development of a USP 4 dissolution method. For example, the CP 7 allows to test the 3 recommended USP flow rates (4, 8 and 16 ml/min) during the same test.

Another advantage of this pump is the automatic calibration/validation feature. For this purpose, the pump is linked to a balance (optional) and printer (optional). The pump automatically checks and adjusts its flow rate channel per channel based on user-defined volumes. The calibration protocol is then automatically printed out.

Configurations to fit your dissolution test

Analytical options and versatility

When it comes time to analyze the dissolution samples, the SOTAX CE 7smart can be connected to multiple components affording the end user greater flexibility. The CE 7smart can be fitted with either a UV-VIS spectrophotometer for „on-line“ UV measurements or a fraction collector to collect portions of samples for analysis by HPLC.

USP compliant at any volume

USP 4 the "flow-through" method does not have volumetric restrictions like USP 1 & 2. USP 4 can be used to test dosage forms in a very wide range or volumes $\approx 15 \text{ ml} \rightarrow \infty$. The CE 7smart is ideal for use with dosage forms containing insoluble API's. Without volume restrictions USP 4 will allow the dissolution to be performed at optimal sink condition.

Open system

An open system configuration is ideal for dosage forms that require large volumes of solvent to keep within sink conditions. The SOTAX CE 7smart can be configured to run a dissolution test always using fresh solvent or media, and it allows for easy media or pH changes, using the media selector. An open system is recommended when the API is insoluble and large volumes of media are required. Multiple analytical finish options are available.

Closed system

A closed system configuration allows for dosage forms to be tested in as little as 15 ml total volume. Small volumes can be ideal for „low-dose“ dosage forms. In a closed system, the test is run much like USP 1 & 2 as the results are taken as a cumulative dissolution curve. Closed systems are ideal for dosage forms such as drug-eluting stents, microspheres or implants. Multiple analytical finish options are available for closed systems.