Xtend™ Dissolution Testing

USP
1/2/5/6

sotax

Whether you perform routine testing in QC or need to execute DOE studies in R&D – Xtend™ allows flexible automation of your dissolution tests as needed. Changing throughput requirements? Standardized Xtend™ Modules can be combined to differently automated dissolution systems – making method transfer and scale-up easier than ever.

From manual baths to full end-to-end automation with multiple networked systems, Xtend™ is one platform for all your dissolution needs.

Ready for tomorrow. Today.

USP 1 — Basket

USP 2 — Paddle

USP 5 — Paddle over disk

USP 6 — Rotating cylinder

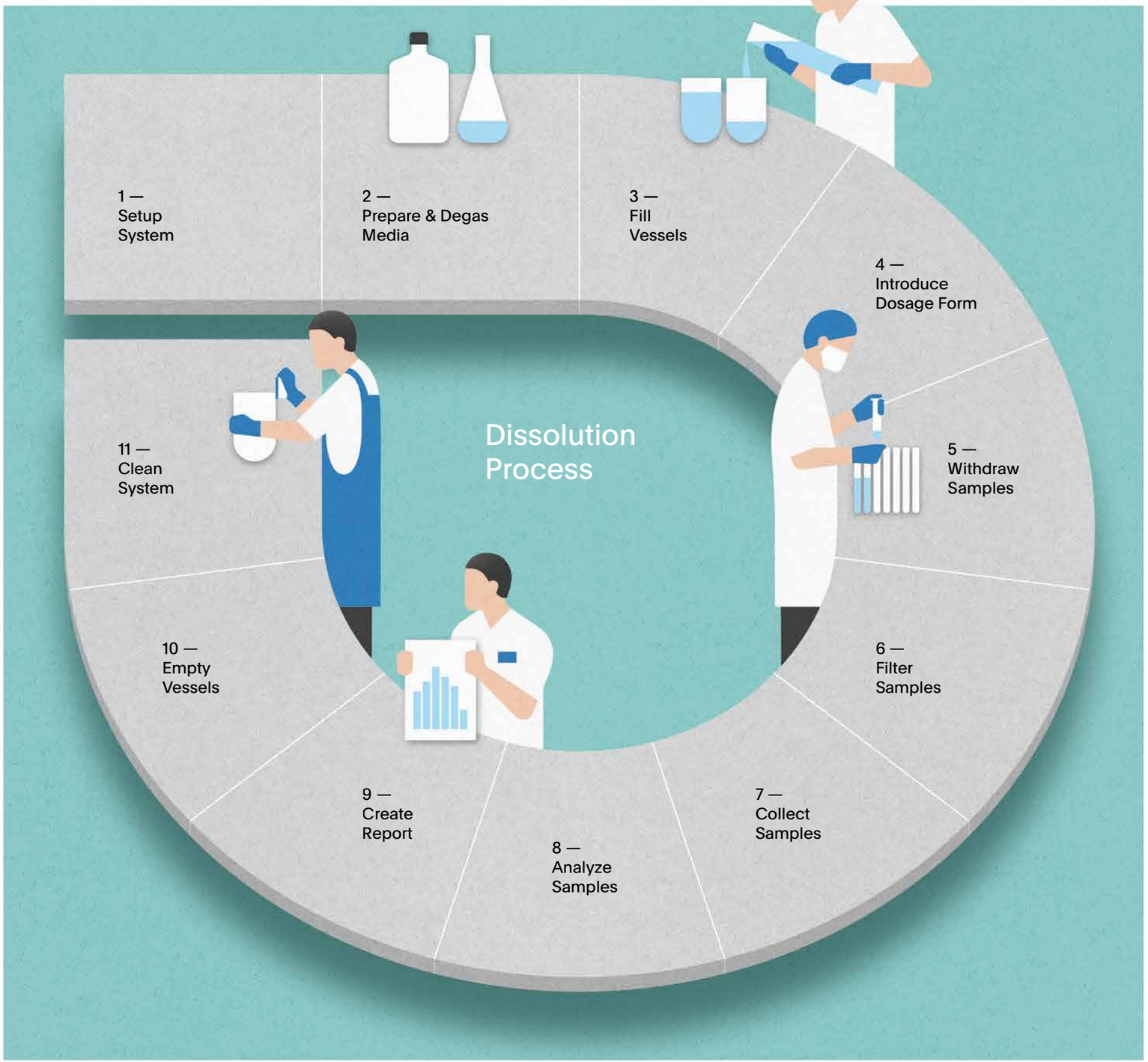
Contents

Xtend™

What do you not want to automate?

How much time does your laboratory team spend on tasks such as filling vessels and cleaning? Automation allows qualified staff to focus on critical processes rather than spending their time on supporting activities. With Xtend™, all dissolution steps from media preparation to cleaning of the system can be performed automatically.

Xtend™
Dissolution Process



One platform for all your dissolution needs.

Whether you perform routine testing in QC or need to execute DOE studies in R&D, Xtend™ allows flexible automation as needed. From manual baths to full end-to-end automation with multiple networked systems, Xtend™ is one platform for all your dissolution needs.

Manual — AT Xtend™

Increase repeatability of your manual tests with user-guided operation for key activities such as staggered sampling. Automatically record individual vessel temperatures and take traceability to the next level with CenterView™ video monitoring.

M Manual

Semi-Automated — ATS Xtend™

Automate sampling and filtration of your dissolution methods – including media replacement and pH changes. Collect samples offline, take UV-Vis measurements in real-time, or automatically inject collected samples into your HPLC system.

S Semi-Automated

Fully Automated — ATF Xtend™

Automatically execute and record all dissolution steps of multiple test runs. True end-to-end automation and 100% unattended operation from vessel filling to sampling & filtration, and self-cleaning of the entire system between tests.

F Fully Automated

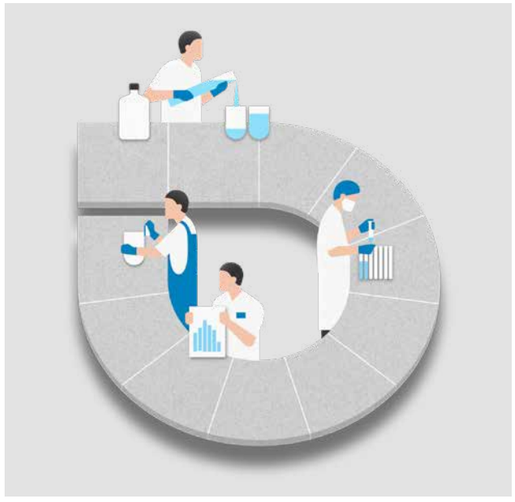
Modular.
Seamlessly combine Xtend™ modules for different throughput requirements – from manual to fully automated dissolution.

Scalable.
Identical components simplify method transfer and scale-up. Keep in place what is already used, described, and validated.

Future-proof.
Secure your investment today and flexibly manage tomorrow's demands with Xtend™ dissolution systems.

Only perform manually what really counts.

Repeatable operation of simple laborious steps is at the heart of automating your dissolution process. Changing throughput requirements? Standardized Xtend™ modules can be combined to differently automated dissolution systems – making method transfer and scale-up easier than ever.

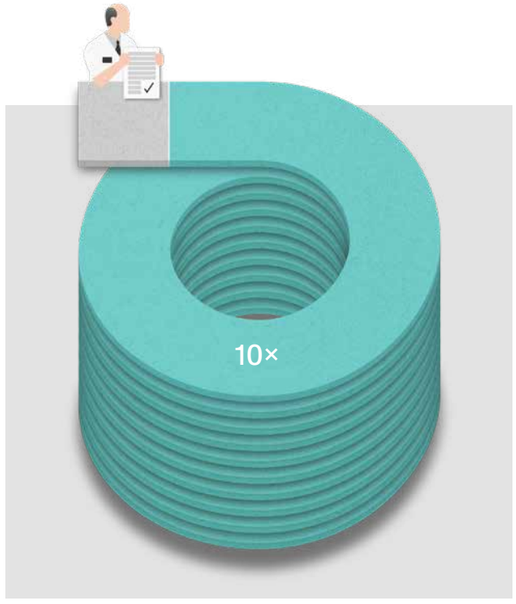


Manual.

User-friendly EasyTouch™ operation actively supports repeatable execution of manual tasks. Laboratory staff is guided through critical process steps such as staggered dosage form introduction and taking samples manually. All method parameters including multiple timepoints and even pH changes during the test can be preprogrammed to prevent mistakes from happening.

Semi-Automated.

Take samples the same way every time. Automated sampling & filtration ensures highly reproducible results at all times. Combining standardized Xtend™ modules allows for close timepoints even when pushing through fine filtration or using surfactants. Take full advantage of your system by integrating analytics like UV-Vis or liquid chromatography (HPLC / UPLC).

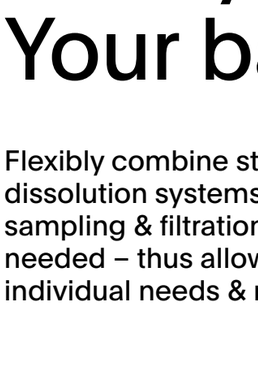


Fully Automated.

Simply automate everything – from media degassing and vessel filling to test execution and self-cleaning. Once the operator has placed all samples to be tested in a multi-batch magazine, the systems performs a series of 100% unattended dissolution runs. Let your Xtend™ system do the work and focus on mission-critical tasks such as analysis and interpretation of results.

Ready for Automation? Your bath is.

Flexibly combine standardized Xtend™ modules to differently automated dissolution systems. Modular design allows to seamlessly automate sampling & filtration, integrate analytics, or add monitoring options as needed – thus allowing to configure Xtend™ dissolution systems to your individual needs & requirements.



Your dissolution bath.

Ready for automation whenever you are. Easy-to-operate manual dissolution bath that can be extended as needed.

Automate sampling.

Take samples the same way every time. Choose from different sampling & filtration possibilities including HollowShaft™.

Add monitoring.

Increase traceability by protocolling individual vessel temperatures or by adding video monitoring for each vessel.

Automate everything.

Add features to automate media degassing, vessel filling & emptying, and self-cleaning for multiple dissolution tests.

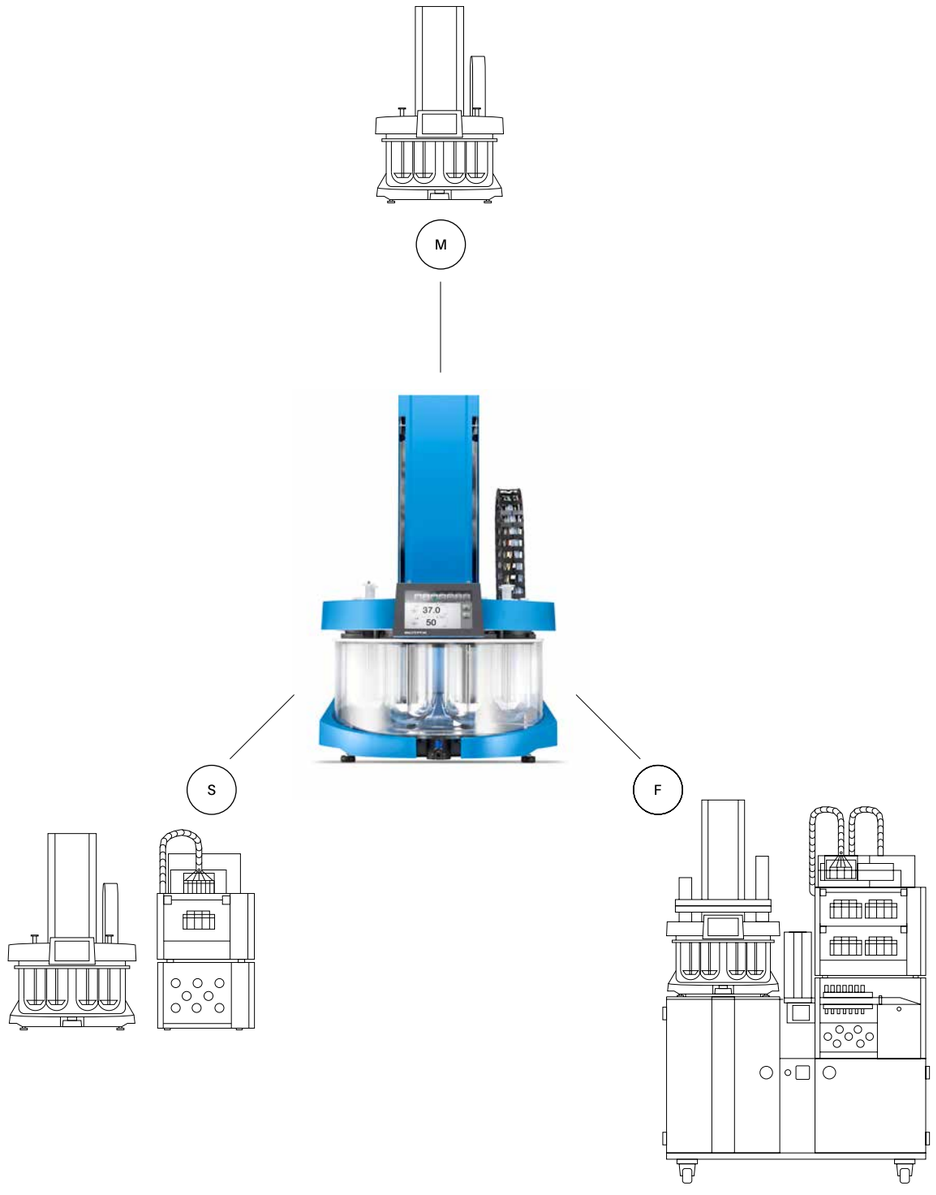
Modular.
Configure your Xtend™ system and chose from various sampling & filtration possibilities to meet different requirements or to mimic existing environments.

Scalable.
Easily fulfil increasing documentation requirements or data integrity policies by adding monitoring options or by automating error-prone manual tasks.

Future-proof.
Xtend™ allows you to flexibly respond to changing requirements, increases lab efficiency, improves data quality, and automates simple repetitive activities.

Bath

The heart of Xtend™ — Your Bath.



USP 1/2/5/6 and more.

From standard paddle (USP 2) and basket (USP 1) methods to alternative dissolution tests. Different vessel designs, materials, and apparatus types available.

Sampling & Filtration.

Mimic existing environments for comparability of results. Take samples with HollowShaft™, AutoLift™ cannulas or resident probes – and use different types of filters.

Integrated Monitoring.

Increase traceability of your data and simplify investigations with temperature protocolling of each vessel and CenterView™ video monitoring.

Unobstructed View.

See what's going on. The circular bath design provides for excellent observation possibilities and ensures an unobstructed view of all vessels.

AutoCompliance™

No adjustments needed and proven to have the lowest wobble rating in the industry. Built-in regulatory compliance with fixed shaft height and self-centering vessels.

Take control of your data.

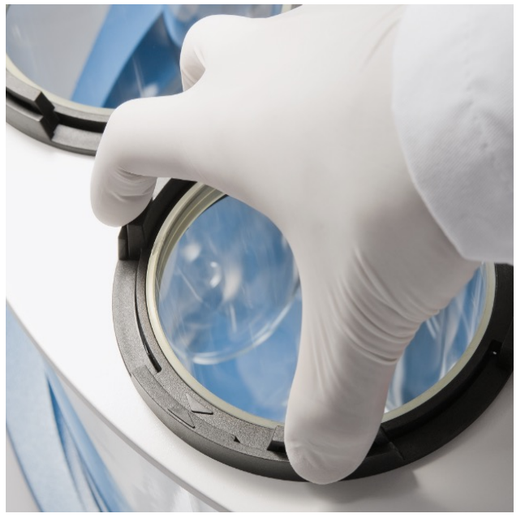
From intuitive stand-alone operation with EasyTouch™ to fail-safe networking of multiple dissolution systems with q-doc® data management software.

Temperature control.

The round bath design ensures very homogenic vessel temperatures thanks to optimum water circulation. It also provides for easy cleaning without any corners.

AutoCompliance™ — Compliant by Design.

Simply close your bath and you are ready to go. 100% compliance without time-consuming adjustments. Proven to have the lowest wobble rating in the industry, SOTAX dissolution baths excel with self-centering vessels and fixed shaft height since 1973.



Self-centering.

Highly accurate vessel centering with quick-lock system for fast change-over and easy handling.

No adjustments needed.

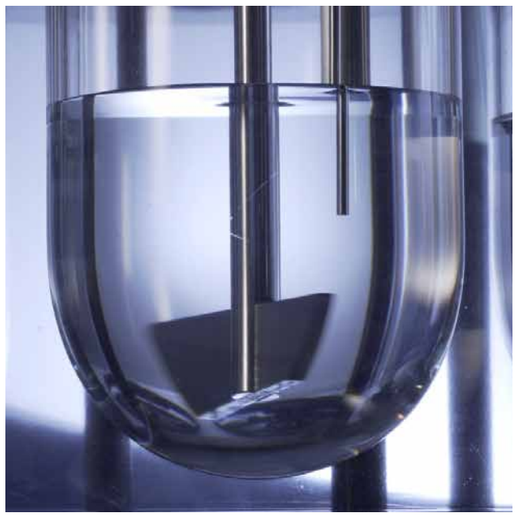
Need to change from paddle to basket method? The fixed shaft height guarantees compliance without any adjustments.

Video Monitoring.

Record the dissolution process in each vessel for R&D visualization or simplified OOS troubleshooting.

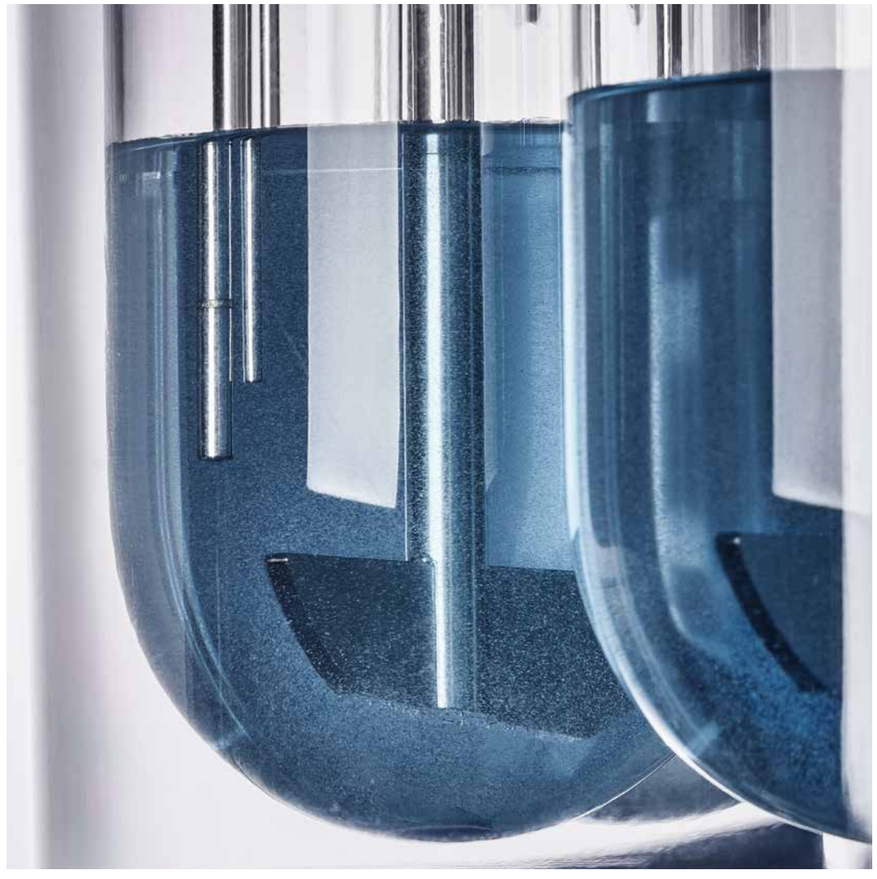
Temperature Monitoring.

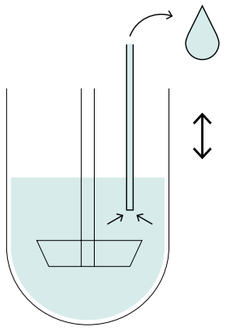
Protocol and report individual vessel temperatures anytime – e.g. before test start and at each timepoint.



How would you like to take your samples?

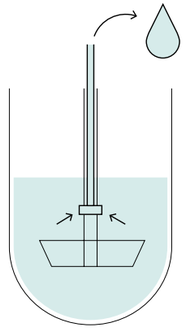
Different sampling possibilities and various filtration options allow to mimic existing environments for comparable test conditions. Regardless of the preferred sampling method, your Xtend™ system ensures repeatable sampling positions and results you can rely on.





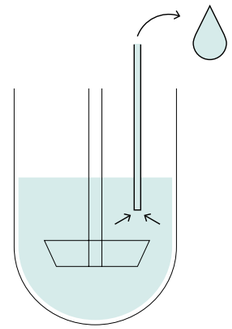
AutoLift™ sampling.

Samples are automatically withdrawn from vessels using motorized AutoLift™ probes. Reproducible sampling positions in full compliance with USP <711> and other harmonized Pharmacopeia provide for comparable testing conditions. Available for all Xtend™ dissolution baths and all automation levels.



HollowShaft™ sampling.

Unique SOTAX HollowShaft™ technology allows to withdraw samples directly through the paddle/basket shaft. Fully compliant with USP <711> and other Pharmacopeia, the HollowShaft™ is proven to virtually eliminate undesired hydrodynamic effects that may impact dissolution results.



Resident probes.

You can also operate your Xtend™ dissolution systems with stationary sampling probes if required by a particular method. The cannulas remain at a fixed positions inside the vessels throughout the dissolution test to withdraw samples at the desired timepoint(s).

Filter type	AutoLift™	HollowShaft™	Resident	Pore size	Membrane material	UV	HPLC	UPLC
Tip filter / Full flow	●		●	1 µm – 45 µm	PE, PVDF	●	●	
Disc filter	●	●	●	0.7 µm – 2.7 µm	Glass fiber	●	●	
Syringe filter	●	●	●	0.2 µm – 1.0 µm	PTFE, Nylon, PVDF, PP	●	●	●

Different Methods. One Solution.

In addition to standard paddle (USP 2) and basket (USP 1) methods, you can run a wide range of methods requiring different vessel & apparatus type combinations on your Xtend™ dissolution system. All shafts and vessels are identified with a unique SOTAX serial number.

Vessel types.

Broad range of different vessel styles, volumes and materials including mini vessels, China vessels and peak vessels.

Glass vessel (1 liter)

Polycarbonate vessel (1 liter)

UV-protected vessel (1 liter)

Glass vessel (2 liters)

Mini vessel

Apex vessel

China vessel

Apparatus types.

Different shaft designs for standard paddle & basket methods plus a great variety of alternative dissolution methods.

Basket (USP 1)

Basket (USP 1)

Paddle (USP 2)

Paddle (USP 2)

Rotating cylinder (USP6)

Rotating cylinder (USP6)

China paddle

Mini paddle

Intrinsic dissolution

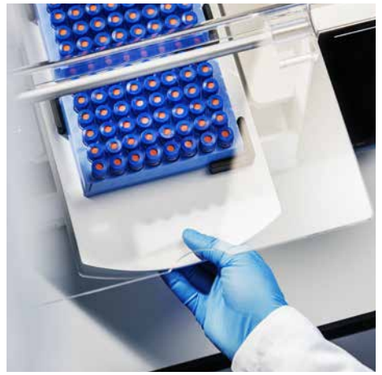
Paddle over disk (USP5)

Paddle over disk (USP5)

Analytics

Offline Collection or Integrated Analytics?

All samples need to be analyzed – either in a separate step with stand-alone analytical devices or as an integrated module of your Xtend™ dissolution system. As online systems combine both test execution and analytical finish into one process, they allow for consolidated reporting, ensure data integrity, significantly reduce time-to-result, and eliminate time-consuming & error-prone manual activities such as re-racking.



No more re-racking.

Collect samples in standardized HPLC vial plates from different manufacturers and simply place the complete vial plate into your chromatography system.

Fast degrading products.

Optional cooling inside the sample collector prevents degradation of samples awaiting offline or online LC analysis.

Immediate results.

Take UV-Vis measurements in real-time and report analytical results & recorded test conditions in one consolidated protocol.

UV

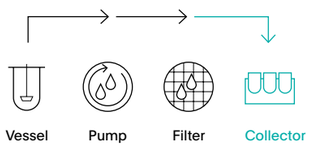
Direct injection.

Automatically inject collected samples into your liquid chromatography system (HPLC / UPLC) and reduce time-to-result to an absolute minimum.

LC

Offline.

Remain 100% flexible without dedicating your system to any analytical method. Offline systems automatically collect samples in standardized tubes, capped vials, or vial plates for manual transfer by the operator to an analytical device. For methods with multiple timepoints, the system can automatically replace withdrawn sample volumes if needed.



Maximum flexibility

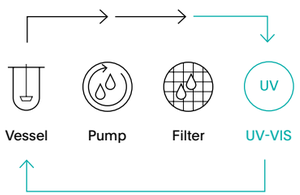
Collection in tubes, closed LC vials, and HPLC vial plates

Automatically replace withdrawn volumes for DR/MR methods

Optional cooling of collected samples

UV Online.

Gather analytical data in real-time and eliminate waiting times by integrating a UV-Vis spectrophotometer into your sampling process. Withdrawn volumes are immediately returned to the vessels – no medium replacement required. Analytical results including recorded test conditions are reported in one consolidated test protocol at the end of each dissolution run.



Results in real-time

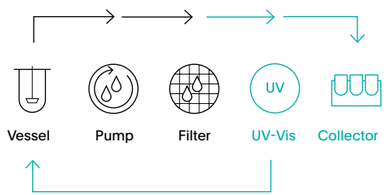
Sample as often as every 60 seconds from each vessel

Single wavelength and multi-component analysis

Analytical results & test conditions in a single report

UV On-/Offline.

Get the best of both worlds and combine the advantages of UV Online with the flexibility of an Offline system. Take UV-Vis measurements in real-time and collect samples for more complex analytical methods offline. Add cooling of collected samples if needed and let the system perform medium replacement or pH changes without any operator action needed.



The best of both worlds

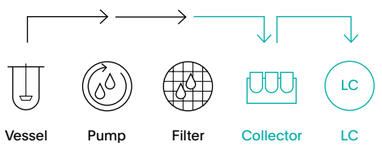
Integrated UV-Vis analysis in real-time

Collect samples offline for HPLC / UPLC analysis

UV-Vis results & test conditions in a single report

LC On-/Offline.

Collect samples and automatically inject them into a connected HPLC / UPLC without any manual transfer. Simultaneously withdrawn samples are temporarily buffered and then sequentially injected one-by-one into your chromatography system. Reduce the time from sampling to HPLC analysis to an absolute minimum – particularly for fast degrading or other critical products.



100% unattended injection of samples into HPLC / UPLC

No manual transfer

Fine filtration down to 0.2 microns prior to UPLC injection

Minimum time from sampling to HPLC results

Systems

AT Xtend™ Manual

Simple & User-friendly Operation

Maximum Flexibility

Integrated Monitoring Functions

AutoCompliance™

Data Integrity

q-doc® Data Management

Share methods between multiple dissolution systems

Consolidated batch reporting with central MS SQL® database

Import jobs from your LIMS and export protocolled test data

Use your Windows® password with active directory (AD) integration

Flexible & Compliant

Manual sampling with AutoLift™, HollowShaft™ or resident probes

6 – 8 vessels

Circular bath design for excellent visibility of all vessels

AutoCompliance™ with fixed shaft height and self-centering vessels

CenterView™ video monitoring

Manual or motorized bath closing mechanism to prevent evaporation

EasyTouch™

User-guided dosage form insertion and sampling procedures

System preparation checklist to help operators in performing all preparation steps

Audible signal to alert operator for manual tasks

Use pre-programmed methods or simply operate in manual mode

Advanced user administration with user groups, permissions, and configurable password policies

Product version control for full traceability of all method changes

Export reports as PDF or allow access to internal file share (SFTP)

Simple draining of water bath

ATS Xtend™ Semi-Automated

Unattended
Sampling & Filtering

Collect samples offline
or integrate analytics

Timed start with
automated dosage form
introduction

Assisted system cleaning

Data Integrity

Stand-alone operation with
EasyTouch™ control or
data management with q-doc®

Automated replacement
of withdrawn sampling volumes
(media replacement)

Automated pH change
(media addition)

Integrated sample analysis
with UV-Vis or HPLC / UPLC

Automated Sampling with
HollowShaft™, AutoLift™ probes,
or resident cannulas

Temperature monitoring
of all vessels

Timed start with
automatic tablet drop

Integrated CenterView™
video monitoring

System-supported
cleaning routine

Optimized pumping for your
application (piston pump /
syringe pump / peristaltic pump)

Automatic syringe filter change

Sample collection in tubes,
vials, or vial plates

Automate Sampling. Integrate Analytics.

Take your samples the same way every time. Automated sampling with identical withdrawal positions ensures repeatability – and allows for fast sampling timepoints pushing through fine filtration even when using surfactants. Take full advantage of your semi-automated system by integrating analytics.

Offline

Automatically withdraw, filter, and collect samples in tubes, vials, or vial plates.

UV

UV Online

Integrated UV-Vis analysis of samples in real-time for each timepoint.

UV

UV On-/Offline

Get the best of both worlds. Online UV-Vis measuring and offline sample collection.

LC

LC On-/Offline

Automated injection of collected samples directly into your HPLC / UPLC.

Share Modules. Double Capacities.

Double your throughput and execute two dissolution tests with one semi-automated system. Available for all analytical configurations, double systems* allow simultaneous sampling from two dissolution baths into one sample manager or one analytical device.

Double Offline

Automatically collect samples from two baths in one SAM Sample Manager.

UV

Double UV Online

Real-time UV-Vis analysis of two dissolution tests with one spectrophotometer.

UV

Double UV On-/Offline

Share your Sample Manager and UV-Vis for online testing and offline collection.

*Double systems require two pumps.

ATF Xtend™ Fully Automated

Quick-change tablet magazine for multiple test runs

Sampling with HollowShaft™ or AutoLift™ probes

Temperature monitoring of all vessels

In-vessel volume monitoring

Automatic emptying of vessels

Efficient self-cleaning with integrated spray nozzles and programmable cleaning routines

Integrated media preparation with vacuum degassing

Gravimetric volume control

Integrated sample analysis with UV-Vis or HPLC / UPLC

Sample collection in tubes, vials, or vial plates

Automatic syringe filter change

Fast and powerful piston pumps for highly efficient sampling

Stand-alone operation with EasyTouch™ control or data management with q-doc®

- Multiple Unattended Runs
- Self-cleaning
- Integrated Media Preparation
- Automated Sample Collection & Analysis
- Data Integrity

True Automation. 100 % Unattended.

Repeatable operation of simple laborious steps is the heart of the fully automated system. Execute and record all steps from media preparation to vessel filling including gravimetric verification of vessel volumes, sampling & filtration, to cleaning of the entire system.

Fill.

Fill vessels automatically and record individual volumes. Media is dispensed down the vessel wall avoiding media reaeration. Delivered volumes are confirmed gravimetrically and in-vessel volumes are monitored throughout the test.

Test.

Take samples the same way every time – from repeatable sampling positioning to automatic filter change and replacement of collected sample volumes. Require a pH change? Let your system do it for you.

Empty.

No need to remove vessels anymore. The self-cleaning system automatically empties all vessels on completion of a test run and starts the washing routine.

Clean.

Clean in place the same way every time – and let your system prepare itself for the next run. Have a sticky product? Customized self-cleaning procedures can be saved per product allowing for enhanced routines.

Fill, Rinse. Repeat.

Prepare.

Prepare media in-line with concentrate using your house DI source or connect different media types for automated preparation. Save time by preparing the next medium while a test is running.

Degas.

No more helium sparge!
Pull a vacuum on your media at temperature for complete & cost-efficient deaeration. Use effectively on all media types including foaming media with surfactants.

Clean.

Power wash the tank for efficient cleaning. Robust cleaning routines facilitate easy media change for MR methods as well as entirely different products within a series of test runs.

SmartAdd™ Keep on running.

Make your testing continuous and prepare a new series of tests while the system is running. Whether you automate dissolution DOE in R&D or routine testing in QC, SmartAdd™ allows flexible interaction and avoids downtime. Simply exchange complete tablet magazines to immediately start a new sequence.

SmartAdd™
it to the sequence

Design of Experiment (DOE)

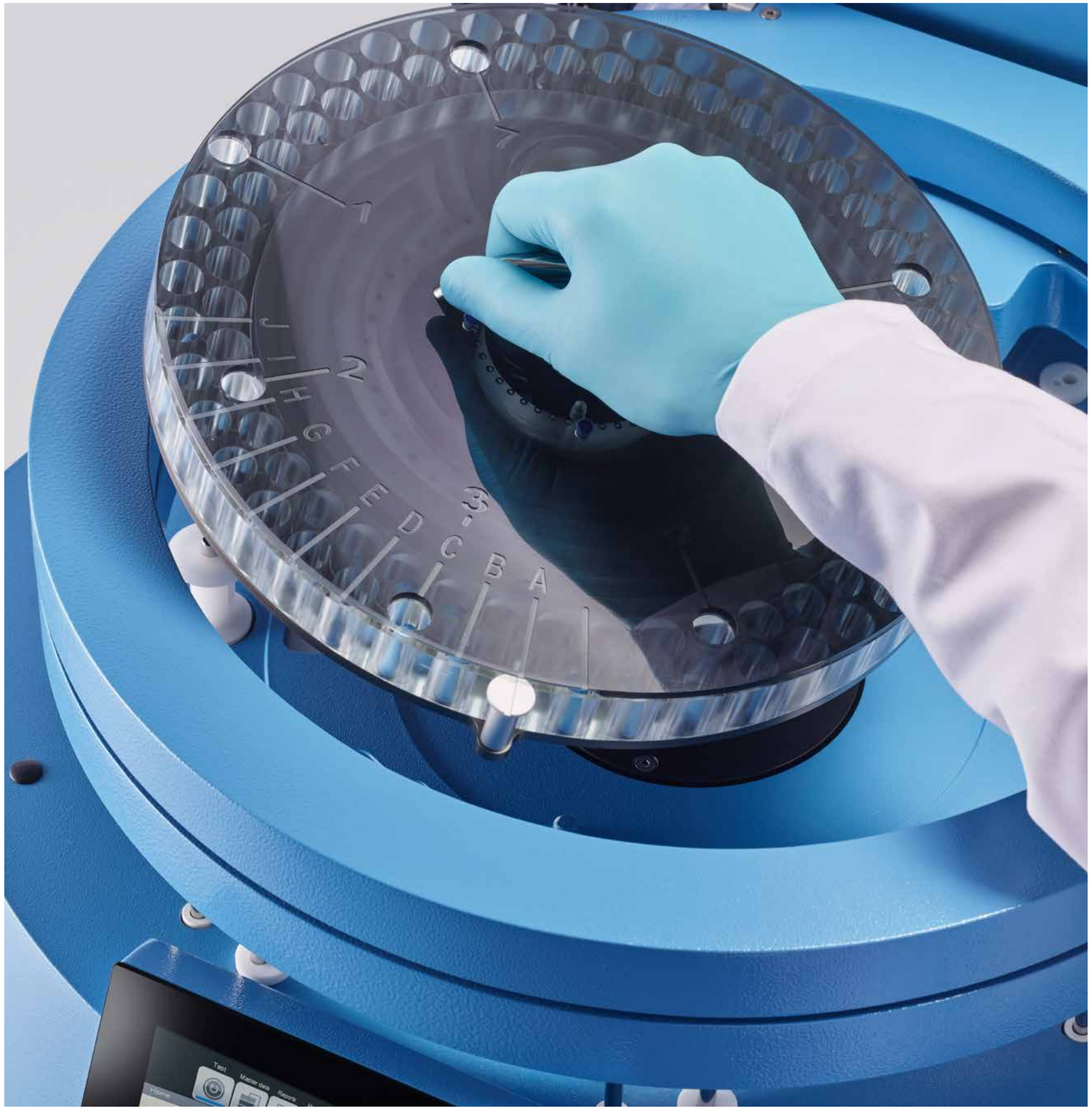
Decide to include another parameter into your DOE study?

Release Testing

Receive a new lot from production for urgent testing?

Stability Testing

New stability timepoint comes into the lab?



Baskets & Sinkers. Automated.

The optional RS robotic station seamlessly integrates with all fully automated ATF Xtend™ configurations. Retrofittable in the field, the compact station allows unattended execution of multiple dissolution runs with baskets (USP 1) and sinker-based paddle methods (USP 2).

Basket exchange.

On completion of a test all used baskets are removed and replaced by new baskets.
The RS provides safe storage of prepared baskets for up to 32 unattended dissolution tests.

Sinker retrieval.

The RS robotic station automatically removes small and large sinkers from vessels upon test completion. Used sinkers are collected in a separate container for cleaning.

Efficiency. Maximized.

Maximize the efficiency and repeatability of your dissolution tests with full end-to-end automation. From media preparation to self-cleaning – automate all process steps for highly effective & fully unattended execution of multiple dissolution runs.

Offline

Automatically withdraw, filter, and collect samples in tubes, vials, or vial plates for up to 90 timepoints.

UV Online

Integrated UV-Vis analysis of samples in real-time for a virtually unlimited number of timepoints.

UV On-/Offline

Unlimited real-time UV-Vis measuring and offline sample collection for up to 90 timepoints.

LC On-/Offline

Automated injection of collected samples from up to 90 timepoints directly into your HPLC / UPLC.

SOTAX Group

SOTAX Group

Reliable automation of simple laborious steps and finding innovative solutions for your testing problems has been our mission since 1973. From the world’s first flow-through dissolution tester to self-cleaning systems, patented tablet alignment, and user-friendly data management – SOTAX engineers specialize in making testing easier, faster, and more precise for you.

Knowing that there is more to a solution than innovative technology, we are proud to have the largest field service organization in our industry. Our global team of application experts, product specialists, and service engineers are looking forward to supporting you whenever you need it.

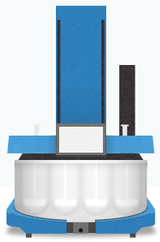
Whether you need help with an application problem or would like to learn more about possible efficiency gains in dissolution testing, physical testing, or automated sample preparation – SOTAX is your one-stop solution.

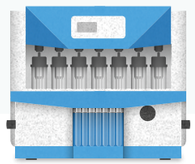
Product segments.

Data Management

Dissolution Testing

USP 1/2/5/6	USP 4
• Manual • Semi-Automated • Fully Automated	• Offline • UV Online • UV On-/Offline





Automated Sample Preparation

Physical Testing

Hardness	Disintegration
Friability	Weight
Tapped Density	Flowability
Cap Torque	

Services & Support

Pharma Services

SOTAX Worldwide.

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