ALMAC

Partnering to Advance Human Health

Case study

Sotax AT MD Semi Automated Dissolution System

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Almac has invested in a Sotax AT MD Benchtop Dissolution system at its US analytical laboratories. This is a fully automated dissolution system for USP one (Basket Method) and USP two (Paddle Method - Tablets, Capsules& Sinkers). It can accommodate large volumes for immediate release tablets and handle difficult methods for extended release.



Basket station



Robotic arm



AT MD dissolution bath



MD station



SAM sample manager

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Interview with Joseph Forth, Director Analytical Operations about the implementation and benefits of the Sotax AT MD Benchtop Dissolution system

What was the key driver in investing in robotic equipment?

Investing in robotic equipment for lab testing companies is primarily about increasing capacity and throughput and Almac's primary reason for investing was no different.

The Sotax AT MD Semi Automated Dissolution System investment was critical to satisfying client demand as the system can potentially run twenty-four hours a day, seven days a week which instantly provides the efficiency and capacity boost we required. This has been a great strategy for our growth because we have increased output without the additional time and cost of infrastructure investment.

What is dissolution testing and why is it so important?

The formal definition from the United States Pharmacopeia explains dissolution testing as "the process in which a substance forms a solution." It is critical in drug development to understand how long the drug form - whether it be a tablet, capsule, softgels, etc – takes to dissolve in the body and evaluate its therapeutic effectiveness.

Is there one significant benefit to implementing this technology?

One of the main technology benefits is additional improvements in quality and compliance, which is extremely important.

When performing dissolution testing, an odd result can occur occasionally. For example, six vessels of six different tablets could be running and five of them perform as expected, but the sixth one has a significant anomaly. Unless you are observing the whole test continually, you would not be aware if something unusual happened in that vessel that may have caused the anomaly, e.g. the capsule might have gotten stuck to the shaft, or maybe the tablet or capsule didn't break apart and come open like it was supposed to, etc. There are all kinds of possibilities, and you are never going to have an assignable cause or be able to investigate without a technology like the Sotax.

Within our system there are cameras over every vessel, and it is possible to record either the entire run or just certain points throughout the run so that we can go back if a situation like the above occurs.

Are there any other key benefits?

Absolutely! There are many advantages of automated dissolution testing: Automating the dissolution process increases lab efficiency, improves data quality, and eliminates redundant, error prone tasks in the laboratory.

- **Improved data reliability** - Each dissolution test is performed the same way, every time, for more precise datasets.

- **Increased productivity** - Automated dissolution improves laboratory productivity by reducing cycle times and completing more work with existing resources. Automated dissolution provides "walk away time" for operators, allowing more time for other critical activities (i.e., method development, process validation, data checking and verification).

- **Shortened cycle times**

- **Enhanced safety** - Automation improves safety by reducing exposure to hazardous solvents and compound materials used in testing. In addition, automation reduces ergonomic stress by eliminating common repetitive tasks, such as sampling and filtering.

- **Reduced Out Of Scope results** – As discussed previously, automated dissolution testing reduces the potential for human error and simplifies the investigation process. Video monitoring capabilities can be utilised to evaluate "real time" dissolution progress and provide valuable investigative information.

- **Reduction of operator variability & increase of reproducibility**

How has the Sotax Automated Dissolution system enhanced productivity?

Once the system qualifications were complete, our team used it immediately on customer projects. We can now perform more dissolution testing than we could with our standard lab equipment.

Without this investment it is likely we would have had to turn away clients due to the lack of capacity. Clients are now assured of our capacity to do what they are looking for, and that we can get it done within the timeline that they are working towards. A project that might have taken two months before is now only taking a month. When clients visit, we have been showing them the machine and it puts us in a great position to talk through these benefits and its applicability to their projects. To be able to say we can guarantee capacity, with speed, and with improved quality controls is a great story.

Key features of Sotax AT MD Semi Automated Dissolution System

From pre-test to runtime to post-test system cleaning streamlined workflow simplifies routine operation.	•Semi-automated bench-top dissolution system •Basket (USP 1) and paddle methods (USP 2) as well as sinkers •Runs up to 8 unattended batches •Driven by the 21 CFR Part 11 compliant MD software •Compliant with all harmonized pharmacopeia requirements •Video monitoring capabilities to provide "real time" dissolution progress and provide valuable investigative information
Auto-centering vessels	Time-consuming vessel set-up is eliminated with the AT's auto-centering quick-lock system. which guarantees highly accurate vessel centering.
Fixed shaft height	All shafts are self-centering and no adjustment of shaft height is required.
Compliance by Design	The fixed shaft height and vessel positioning guarantees 100 % compliance without requiring time-consuming adjustments
R&D	Allows for many different runs and ease of method transfer. For applications in R&D, automation can offer distinct advantages with 100% unattended execution of Design of Experiment (DOE) tests.
QC	Automated solutions offer high throughput when needed by allowing for many unattended runs of the same method

Almac supports dissolution testing for a range of different drug product formulations including tablets, capsules and softgels. We routinely perform comparative dissolution testing for over- encapsulated products. We can also support disintegration testing if required.

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