

Automated Drug Release Testing



Nowadays, drug delivery methods can range from oral, topical, intravenous, to even targeted slow release subcutaneous systems based on (bio)polymers. Also, API characteristics have become more diverse: ranging from small molecules, peptides and proteins to even whole cells in scaffolds for 3D tissue engineering.

However, the main goal of dissolution and drug release testing has not changed: quantities of drug released in *in vitro* test methods need to correlate well with the levels measured in blood. This is not only necessary to ensure that adequate bioavailability and -safety is attained, but forms the basis for product quality, dictating which manufacturing specifications need to be met. *In vitro* release testing is also a valuable analytical tool to investigate and establish product behavior in the various stages of drug product development, enabling a science based and cost-efficient R&D approach.

So, what **has changed** is the number of compendial and regulatory standards for dosage form testing. Even more adaptability is required from the laboratory for non-compendial, novel dosage form testing such as injectable microspheres, hydrogels or nanoparticles and -fibers. Clearly, the one-size-fits-all approach no longer suits the modern requirements of drug release testing. The pharmaceutical industry has covered a long distance since the dissolution testing of tablets and capsules.

There is no need to reinvent the wheel though. Dissolution testing has paved the way for automated and/or online drug release testing, establishing an impressive proven track record for the advantages of automation.

Similar gains are made in automating the new *in vitro* release tests. This is of particular importance in current times where resources are still under stress and more has to be done with less people.



SampleQ works together with the pharmaceutical and (bio)polymer industry to solve these challenges. Increased complexity can be combined with high-throughput testing, while maintaining quality and regulatory compliancy.