Adaptive Perfusion: A Novel In Vitro Drug Release Testing Method for Complex Drug Products

Technology Summary

Drug in vitro release testing (IVRT), also called dissolution testing, is used to measure the extent and rate of drug release from tablets, capsules, ointments, and other formulations. Dissolution testing is necessary in the pharmaceutical industry during drug development to create the optimal drug release profile, and during drug manufacturing as an essential quality control (QC) test to assess batch-to-batch consistency.

Currently available IVRT methods for complex drug formulations rely on diffusion processes using dialysis membranes and have numerous limitations such as lengthy testing times, the inability to analyze the percentage of drug remaining, and dependency on nonadjustable conditions such as concentration gradient and surface area. These limitations make measuring the release of drugs from complex drug products including emulsions, micelles, suspensions, liposomes, and drug-protein complexes analytically challenging.

Adaptive Perfusion (AP) is a new IVRT system that overcomes the limitations of conventional IVRT methods and allows drug release from complex particulate formulations to be investigated. This technique operates based on the principle of the pressure-driven separation by tangential flow filtration (TFF) rather than the rate-limiting passive membrane diffusion. Unique features of AP are the pressure gradient and the size-based separation that can be adjusted based on the type of formulation being analyzed, thus overcoming the limitations encountered in other IVRT methods.

Potential Commercial Applications

- Development and formulation of new drugs and drugs delivery systems
- Quality Control (QC) during drug manufacturing

Competitive Advantages

- Measures drug release from complex products such as emulsions, micelles, suspensions, liposomes, and drug-protein complexes
- The use of tangential flow filtration speeds the testing and allows greater control of the assay conditions

Development Stage: In vitro data, prototype

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Intellectual Property:

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Product Area: drug development, drug formulations, drug manufacturing, drug production, quality control, drug delivery

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