Test, Hold and Release℠

Sterility | Potency | Endotoxin

Test, Hold and Release (THR℠) is the quality assurance program created by CAPS® (Central Admixture Pharmacy Services, Inc.) to assure that every compounded drug batch in our 503B outsourcing facilities meet specifications for sterility, endotoxin, and potency, environmental monitoring and visual inspection prior to release. THR is a key component of CAPS' 503B quality management system, designed to meet the cGMP-level standard release testing requirements established for 503B registered outsourcing facilities in the Drug Quality and Security Act (DQSA).

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THR℠ (Test, Hold and Release℠) is the quality assurance program embraced by CAPS® for 100% batch level release testing. Each batch is also accompanied by a Certificate of Release (available online) to include lot number, compounding date, beyond use date, test specifications, test results, and the signature of a CAPS quality assurance manager. All product is quarantined pending test results for Sterility, Endotoxins, Potency, and Visual Inspection of each batch, as well as Environmental testing during each compounding session of every product.

High-quality standards are further strengthened with the implementation of THR. When it comes to patient safety and your reputation, insist on 100% batch level release testing for every batch that comes from 503B outsourcing facilities. Insist on CAPS.

Essential Elements

Sterility Testing: BacT/Alert® 3D Microbial Detection System's advanced instrumentation reduces incubation and testing time from two weeks to 3-7 days. It is validated to be comparable to USP <71> sterility tests. A colorimetric sensor and reflected light determine the amount of carbon dioxide (Co2) produced as the organisms metabolize substrates in the culture medium.

Endotoxin Testing: The Endoscan-V™ Kinetic Turbidimetric System is an endotoxin measuring system, verified and validated to be consistent with FDA requirements. It performs requisite calculations and batch reports for product release (conforms with USP Chapter <85> Bacterial Endotoxin Testing).

Potency Testing: High-precision, Ultra Performance Liquid Chromatography (UPLC) for CSP potency or concentration testing (Acuity UPLC H-Class) provides quantitative analysis of organic compounds to separate impurities and measure the concentrations of drug CSPs.

Environmental Monitoring: Compounding cleanrooms, airflow hoods, workstations, and zones are monitored daily under dynamic conditions for particulate matter air counts, bioburden air counts, and surface bioburden counts. Compounding personnel are monitored for gloved fingertip and gown bioburden counts daily per compounding session. Additionally, product batches pass sterility and growth promotion tests prior to a product release and a Negative Control test is conducted on each day that media is used.

Visual Inspection: Performed for every batch–including Turbidity, Particulate Matter, Color Change, Container Integrity, Label, and Batch Record Verification.


BacT/Alert® 3D Microbial Detection System


Endotoxin Testing


Potency Testing


Environmental Testing

CAPS® is the nation's largest network of outsourcing admixture pharmacies. Founded in 1991, CAPS pioneered the outsourcing of CSPs and delivers high-quality, same-day admixture services and solutions to hospitals and outpatient facilities across the nation. CAPS has three 503B outsourcing facilities that are registered with the FDA to provide sterile compounding services. CAPS also has 22 state-licensed 503A regional pharmacies that dispense labeled, patient-specific prescriptions including parenteral nutrition and chemotherapy.

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