DYNALABS
Quality Assured™

Core Lab Services

DYNALABS' Analytical Testing Services

Testing for Sterile/Nonsterile Drug Dosage Forms and Raw Materials

Whether your test is a time study, an investigational study (adverse event or diversion monitoring), quality-assurance testing, or training/process validation, you can be confident that your test results are accurate.

All your test results are stored and tracked on our secure website, and results can be viewed immediately. A limited amount of test history is also available on the website, allowing you to see trends and alert you to potential issues.

Release testing, also known as lot or batch release testing, is a critical step to ensure quality of substances and drug products.

DYNALABS Core Laboratory Services

RELEASE TESTING

Potency/Purity

Test protocols based on USP <621>, USP <851>, and USP <1225>

FORMS TESTED

- troche
- capsule
- oil
- gel
- cream
- suspension
- tablet
- suppository
- pellet
- aqueous solution
- powder
- lollipop
- foam
- inhalant
- injectable
- paste
- ointment

Sterility

Test protocols based on USP <71>

FORMS TESTED

- all sterile forms

Endotoxin USP 85

Test protocols based on USP <85>

FORMS TESTED

- oil injections
- pellets
- suspensions
- sterile solutions
- aqueous injections
- powders

Particulate Matter

Test protocols based on USP <788> (light obscuration particle count test) and USP <797> (physical inspection) guidelines

FORMS TESTED

- aqueous injections and solutions
- oil injections (physical inspection only)
- medical devices

Microbial Identification

Test protocols include gram staining, microscopic inspection, and amplification of the DNA of contaminating organisms.

FORMS TYPICALLY TESTED

- positive media fill tests
- bench and/or hood swabs
- settling plates
- contaminated samples

Specific Gravity

Testing protocols based on USP <841>

FORMS TYPICALLY TESTED

- liquids
- oils
- creams
- ointments
- gels

pH

Test protocol based USP <791>

FORMS TESTED

- aqueous injections and solutions

DYNALABS™ Quality Assured™

Call 888.396.2522 *for your solution today*

MarketingTechServices@dynalabs.us **for information about Method Feasability & Stability Profile Testing**

Validation Services

For hospitals and compounding pharmacies, DYNALABS can establish Beyond Use Dates that keep patients and your organization protected. We perform stability-indicating tests (three lots for consistency), following USP storage guidelines for the specific drug, to derive the correct dating. Dating is based on historical data that we have gathered on selective drugs with different variables.

Other validation tests include:

DISSOLUTION

Test protocol based USP <805> and <1225>

- capsules
- tablets

METHOD DEVELOPMENT

Protocol includes the following parameters:

- precision
- limit of detection (LOD)
- limit of quantification (LOQ)
- accuracy
- linearity
- range
- specificity and sample solutions
- robustness
- system suitability
- ruggedness
- standard & custom forged degradation
- stability of standard

Preservative Effectiveness

Protocol based on USP <51>

- all forms of medications with preservatives

STABILITY TESTING

Protocol based on USP <797>

- capsules
- tablets

UNIFORMITY DOSAGE

Protocol based on USP <905>

- Solids (capsules, tablets, pellets, suppositories)
- Liquids (injections, suspensions, gels, ointments, creams)

Process Validation

- Container Closure Integrity Test
- Aseptic Process Verification (media only)

Additional Tests:

- Stability Testing
- Uniformity of Dosage
- Weight Check
- Uniformity USP 905
- Loss on Drying USP 731
- Dissolution USP 711
- Identification
- Specific Gravity USP 841
- pH
- Growth Promotion (suitability of culture media or plates)
- Microbial Identification (Bacterial and Fungal)
- Fungal (use Sabouraud Dextrose Broth for fungal & mold cultivation)