



COMPLIANCE SOLUTIONS FOR YOUR 503A PHARMACY



THERE WHEN YOU NEED US

EAGLE IS A U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND DRUG ENFORCEMENT ADMINISTRATION (DEA) REGISTERED A2LA ISO 17025 ACCREDITED TESTING/CALIBRATION (CERT.# 3980.01 AND 3980.02) LABORATORY FOUNDED IN 2003 THAT PROVIDES ANALYTICAL CHEMISTRY AND MICROBIOLOGICAL TESTING, CONSULTATION SERVICES, AND OTHER TECHNICAL SERVICES FOR PHARMACEUTICAL MANUFACTURERS, PHARMACIES, MEDICAL DEVICE COMPANIES, AND OTHER HIGHLY REGULATED INDUSTRIES, TO SUPPORT THEIR COMPLIANCE NEEDS.

OUR SERVICE AND PRODUCT OFFERINGS

EAGLE HAS EXTENSIVE EXPERIENCE IN COMPLIANCE SOLUTIONS, TESTING, CONSULTING SERVICES, AND MORE



Our scientific experts excel at helping sterile and non-sterile facilities identify risks, challenges, and opportunities by suggesting and implementing cost-effective, science-based solutions. With Eagle's guidance, you will feel confident with your compliance.

With quick turnaround times, leaders in Rapid ScanRDI® sterility testing, exceptional customer service, and Eagle's variety of services, we are dedicated to being the one-stop shop for compounding and hospital pharmacies.

In addition to laboratory testing, Eagle offers services in consulting, validation, calibration, certification, and environmental monitoring.





BEYOND USP <71> LIMITATIONS

STERILITY TESTING OPTIONS THAT SUIT YOUR PHARMACY NEEDS

SCANRDI® – WORLD'S FASTEST STERILITY TEST

Ideal for aqueous and oil-based, filterable solutions.

1-day results

Celsis®

Suitable for various product types.

7-day results

Bac/T Alert®

Ideal for testing LVP and SVP, ophthalmic, inhalation, cell-based, and tissue-derived products.

7-day results

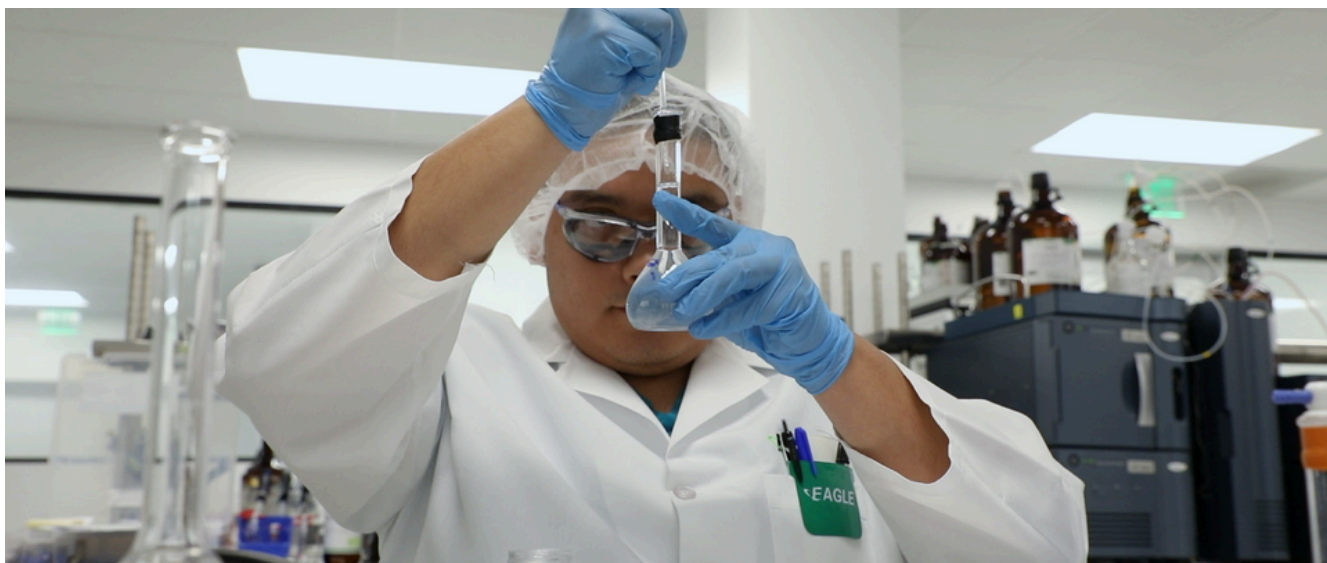
USP <71> Test

- Filtration
- Immersion
- Fluid Path

14 to 18-day results

*Method suitability testing is required for all sterility tests in accordance with USP.





COMMITTED TO QUALITY

SERVICE OFFERINGS

FINISHED DRUG PRODUCT RELEASE TESTING

Potency (API/Preservative)¹

pH

Appearance (color, clarity)

Sterility (USP <71>, Rapid ScanRDI®, BacT/Alert)²

Bacterial Endotoxin Testing²

Particulate Matter

Microbial Examination of Nonsterile Products

USP <60>

USP <61>

USP <62>

Bioburden

Uniformity of Dosage Units

RAW MATERIALS AND CONSUMABLES TESTING

USP/NF Monograph Testing

Growth Promotion Testing

¹ Method shall be stability-indicating and validated to assign Category 3 CSP BUDs and to extend beyond the limits of USP <795>.

² Requires method suitability to maintain compliance.



EXCELLENCE THROUGHOUT

SERVICE OFFERINGS

VALIDATION SERVICES

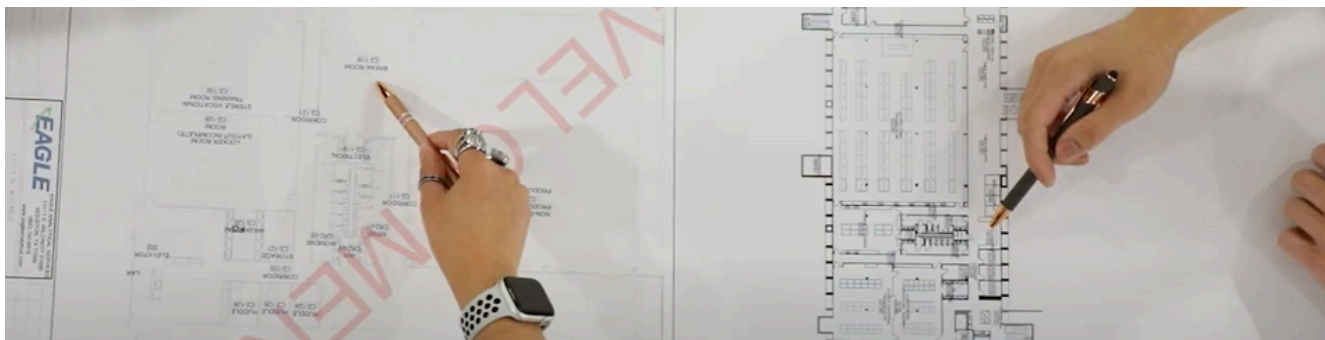
Antimicrobial Effectiveness Testing¹
Stability Indicating Method Development and Validation
Stability Studies²
Method Suitability
Container-Closure Integrity Testing³
Sterilization and Depyrogenation Cycle Validation
Equipment Qualification
Temperature Mapping
Disinfectant Efficacy Testing
Cleaning Validation

¹ Requires method suitability to maintain compliance.

² Must meet all release testing specifications at its intended expiration date.

³ Required for each formulation in its specific container-closure system.

⁴ Required for non-sterile liquid and semi-solid drug products.



ATTENTION TO DETAIL

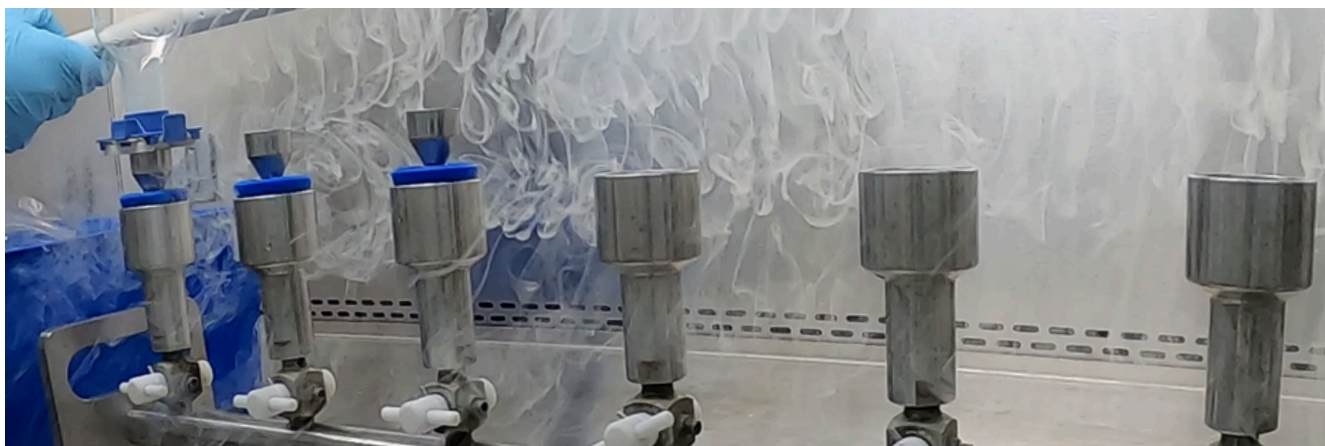
CONSULTING SERVICES, FACILITY DESIGN REVIEW AND MORE

Eagle's consulting services specialize in providing compliance and safety solutions to help facilities minimize risks. These solutions are based on scientific research, pharmacy requirements, and industry best practices. With USP's renewed focus on environmental monitoring frequencies, facility requirements, personnel competencies, garbing requirements, and more, it is essential for your facility to comply with local and federal regulations. Our expert guidance can help ensure your facility meets regulatory standards.

Our consultants have held positions at the Food and Drug Administration, pharmaceutical drug manufacturers including contract manufacturing organizations, 503A compounding pharmacies, and 503B outsourcing facilities.

LET OUR EXPERIENCE WORK FOR YOU:

- Quality Systems Development
- Cleaning Validation
- Disinfectant Efficacy Testing (DET)
- Due Diligence Analysis
- Environmental Monitoring Program Development
- Equipment Qualification
- Facility Design Review
- Gap Analysis Audit/Third-Party Audit
- Mitigation, Remediation, and Regulatory Response Services
- Process Validation
- SOP Development and Implementation
- Training
- USP <800> Compliance



DEDICATION TO PRECISION

CERTIFICATION, CALIBRATION AND QUALIFICATION SERVICES

CLEANROOM FACILITY

PRIMARY ENGINEERING CONTROLS (BCS, LAWF, HOTCELL)

- AIRFLOW VISUALIZATION STUDY (SMOKE STUDY)
- HEPA FILTER INTEGRITY TEST
- DOWNFLOW VELOCITY
- INFLOW VELOCITY
- VIABLE AIR AND SURFACE SAMPLING
- NONVIABLE AIR SAMPLING (PARTICULATE COUNTS)

SECONDARY ENGINEERING CONTROLS

- HEPA INTEGRITY TESTING
- VIABLE AND NON-VIABLE PARTICLE TESTING
- AIR CHANGES PER HOUR (ACPH)
- DIFFERENTIAL PRESSURE TEST
- AIRFLOW PATTERN TESTING

FUME HOODS

EQUIPMENT

CALIBRATION

- BALANCES
- TEMPERATURE AND RELATIVE HUMIDITY SENSORS
- DIFFERENTIAL PRESSURE SENSORS

QUALIFICATION – IOPQ – TEMPERATURE MAPPING

- REFRIGERATOR
- FREEZERS
- AUTOCLAVES
- DEPYROGENATION OVENS
- STABILITY CHAMBERS
- INCUBATORS

Other equipment available upon request.





ENVIRONMENTAL MONITORING SOLUTIONS

TRYPTIC SOY AGAR PLATES - 10 PLATES PER PACK, MINIMUM ORDER - 5 PACKS

Eagle offers TSA plates that are ideal for the recovery of a wide range of microorganisms, including bacteria, yeast, and fungi:

- **90 mm settle plates** are suitable for active and passive air as well as gloved-fingertip sampling
- **65 mm contact plates** can be utilized for active air, surface, and personnel monitoring.

Features and benefits of our TSA plates include the following:

- Supplemented with neutralizers, Lecithin and Tween 80, to inactivate disinfectants present in the environment.
- Convenient room temperature storage to eliminate the need for refrigerated storage conditions.
- Gamma-irradiation to ensure a high level of sterility and minimize the risk of false positive results.
- Self-locking mechanism to ensure the integrity of the sample during handling and transportation.
- Triple-wrapped for quicker movement through ISO-classified areas.
- Include a certificate of growth promotion from the manufacturer and a verification of growth promotion testing performed by Eagle.

Related services:

- Incubation, enumeration of media
- Microbial identification services, complemented by on-site training from our skilled microbiologists. This equips your staff with the necessary expertise to proficiently perform enumeration of media plates, should your facility opt to incubate plates in-house.

For additional information, visit eagleanalytical.com/em





ENVIRONMENTAL MONITORING SOLUTIONS

SURFACESHIELD -DRUG RESIDUE SURFACE WIPE SAMPLING KIT

SurfaceShield is a ready-to-use wipe sampling kit to identify and quantify drug residue contamination on any surface of interest.

Sampling with SurfaceShield is a fast, easy, and convenient method for verifying the efficacy of decontamination and cleaning to support environmental monitoring per USP <800> Hazardous Drugs - Handling in Healthcare Settings.

- **MINIMIZE RISK**
- **MAXIMIZE SAFETY**
- **MAINTAIN COMPLIANCE**

WE TEST FOR:

- **HORMONES**
- **CHEMO DRUGS**
- **HAZARDOUS DRUGS**
- **NON-HAZARDOUS DRUGS**

To learn more about SurfaceShield and view the most up-to-date list of tested drugs, please visit our [page](#).

For pricing visit eagleanalytical.com/product/surfaceshield-wipe-sampling-cleaning-verification-kit



CONTACT US

OUR EXPERTS ARE HERE TO HELP



Through the experience and scientific mastery of our team, we serve CGMP outsourcing facilities by testing routine samples, helping fine-tune formulations, providing feedback on techniques, and more while offering compliance solutions to meet your operational and regulatory requirements.

Visit our [website](https://www.eagleanalytical.com) to learn more about our team, laboratory capabilities, or to receive an initial consultation to discuss your operation's specific needs. We look forward to assisting you.

[WWW.EAGLEANALYTICAL.COM](https://www.eagleanalytical.com)

1.800.745.8916 | [INFO@EAGLEANALYTICAL.COM](mailto:info@eagleanalytical.com) | 11111 S. WILCREST DR. S1000 HOUSTON, TEXAS 77099

