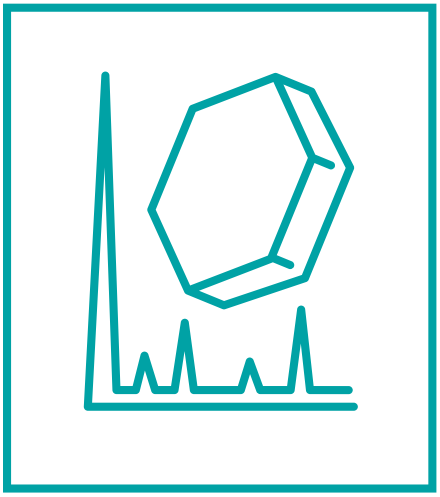
WE'VE GOT ANALYTICAL SERVICES DOWN TO AN EXACT SCIENCE

SPEED PRODUCT DEVELOPMENT AND IMPROVE QUALITY WITH OUR COMPLETE SUITE OF CAPABILITIES.

For decades, AMRI has applied best-in-class solutions to help accelerate the pace of your product development while ensuring performance and quality. We offer method development and validation, stability testing, quality control and spectroscopy services, with unmatched expertise in material science research, separations sciences, container qualification and integrity testing, and extractables and leachables.



Analytical Services

Speed product development and improve the quality of your compound with material science research and analytical testing services.

DELIVERING COMPLEX SCIENCE AND EXPERT SOLUTIONS

Whitehouse Labs and SSCI, divisions of AMRI, offer comprehensive analytical and material science research, providing support from development to market.

Whitehouse Labs provides life science companies with one-stop-shop testing: materials, microbiology, packaging, containers, distribution, medical device and drug delivery testing.

SSCI provides industry-leading, material science research and analytical testing services to help companies in the pharmaceutical, food, agrochemical and other chemical industries develop better products and get them to market more quickly.

Our services span the development continuum for both small and large molecules, from candidate selection in preclinical development through market approval of API and drug product, providing robust support for pharmaceutical development and manufacturing. Offering full cGMP compliance, we are DEA registered to support Schedule I to V controlled substances.

Core Competencies Services Include:

- Preformulation
- Container closure system testing
- Analytical technologies for small and large molecule characterization
- Material science
- Particle engineering
- Analytical development
- Consulting and educational services

amri

Complex Science. Expert Solutions.

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www.amriglobal.com | www.ssci-inc.com | www.WhitehouseLabs.com

Preformulation

We identify fit-for-purpose characterization of the physicochemical properties for your molecule and solid form to assess potential development risks. Our preformulation services range from initial characterization and assessment of your compound to IND consulting services to maximize your understanding of the materials being used in important preclinical and clinical studies.

- Physicochemical characterization
- Solid form screening and selection including salt/cocrystal, stable form and hydrate screening
- Determining equilibrium solubility and establishing pH solubility profiles
- Performing dissolution testing, powder, intrinsic and drug product in aqueous and biorelevant media
- Solubility determination in process solvents, assay and purity profiles, and the isolation and identification of impurities during crystallization process development activities
- Formulation screening to overcome solubility, precipitation, dissolution rate and wettability issues
- Excipient compatibility to support drug product formulation design
- Enabling formulation design for poorly soluble compounds
- Monitoring chemical and physical stability and method development

Analytical Technologies

We offer advanced technologies for analytical testing, such as spectroscopy (IR, Raman, solution and solids NMR, MS); diffraction (XRPD, single crystal structures); mapping and imaging (Raman, IR, NIR, EDS); thermal (microcalorimetry, DSC, TGA, TG-IR); microscopy (polarized-light, SEM); and micromeritics (particle size and surface area).

Method development, validation and transfer services employ both qualitative and quantitative methods for API and drug product. We assess a variety of materials, including drug delivery devices, and assist in determining the origin of issues such as batch-to-batch variability, dissolution issues, bioavailability, flow properties, content uniformity and the presence of unknown materials.

Drug Delivery Device Testing

- ISO 11608: Dosing accuracy for needle-based injection systems
- USP <698> Deliverable volume
- USP <905> Dosage uniformity
- Dimensional inspections
- Mechanical and functional testing
- Cleaning and Sterilization validations
- Extractables and Leachables studies
- Unit dose: MVTR
- Chemical characterization per ISO 10993-18
- Toxicological Risk Assessment by ISO 10993-17
- Biological Risk Assessment by ISO 10993-1

Stability

- ICH conditions (25°C/60% RH, 30°C/65% RH, 40°C/75% RH)
- Non-ICH conditions for client needs
- cGMP storage for production retains with complaint handling
- Photostability studies (ICH Q1B)

Pharmaceutical Materials Testing

Our laboratory has the size and capacity to meet your most demanding requirements. Our USP tests include:

- <643> TOC testing: Water testing and more
- <467> Residual solvents
- <621> Chromatography
- <232>, <233> Heavy metals – ICP-MS
- <401> Fats and oils
- <431> Methoxy determination
- <471> Oxygen flask combustion
- <311> Alginate assay
- Microbiological and biological testing, including: USP <51>, <61>, <62>, <85>, <87>, <1111>, & <1231>

Gas Testing

To qualify gases routinely used in production operations, we offer comprehensive gas testing services including:

- USP/EP nitrogen
- USP/EP carbon dioxide
- USP/EP medical air
- USP/EP oxygen
- USP/EP helium

Material Science

Our team provides a range of screens built to identify the best solid form to overcome developability issues, including bioavailability, or to modulate properties for new uses.

- Polymorph and enabling form screens determine the propensity of different solid forms and their most important properties.
- Amorphous screening and selection offers a development option for crystalline materials with poor aqueous solubility using amorphous materials.
- Discover Screens™ are fast, low-cost screens when you have limited material and a need for rapid delivery timelines during candidate nomination to early development.
- Salt/cocrystal screening and selection seeks to identify multicomponent solid forms with improved properties.

Particle Engineering

The purposeful design of a crystallization process allows for the preparation of batches with the desired purity, crystal form and particle properties. This results in reproducible downstream processes, including filtration, drying, transfer and storage of the bulk drug substance, and critical performance attributes for drug product formulation and manufacturing.

Method Development, Validation and Transfer

Our method development team provides reliable methods for any of your needs from raw materials testing to commercial release of drug substance and drug product. Validation of each method is accomplished according to ICH Q2 guidelines.

Our services include:

- Method development/validation (phase I, II and III)
- Release of drug substance and drug product for clinical use
- Testing of stability samples
- Commercial release of drug substance and drug product
- Transfer of methods developed and validated at SSCI to other testing laboratories

Expert Container and Packaging Testing Solutions

To ensure you meet strict regulatory requirements, our skilled team will identify and conduct the proper test for your product-holding system. We offer scientific expertise, specialized experience and up-to-date training on all relevant regulatory test procedures under USP, EP, JP, CF and ASTM methodologies.

Packaging Validation and Performance Testing

We provide testing to validate your terminally sterilized medical device packaging systems, bringing particular expertise in aging, performance, strength and integrity testing for your sterile barrier packaging.

- ISO 11607 packaging validation: Integrity and strength testing
- Real-time, accelerated aging and environmental conditioning
- Packaging materials: Physical and identification tests
- Packaged product testing: Performance, utility and leakage
- Label adhesion and legibility

Distribution Testing: ASTM and ISTA Package Distribution Simulation Testing

Understand exactly what your product may be exposed to so you can adequately package it. Evaluate your temperature-controlled packaging to ensure that your product remains within its specified safe temperature range.

Distribution Simulation Testing

- Shock, vibration, compression and environmental stress (temperature, humidity, pressure) testing
- Services in accordance with ASTM D4169, D7386, and ISTA 1, 2, 3 and 4 series tests
- Altitude simulation testing up to 40,000 feet
- Environmental conditioning chambers with temperature ranges from -70° to 190°C and 10% to 98% RH can precondition your packages to simulate any shipping environment

Shipment Monitoring

- Shock, vibration, temperature, humidity and pressure

Cold Chain/Thermal Testing

- High-performance Cincinnati Sub-Zero environmental chambers
- Ramp and soak through winter and summer profile

Container Qualification Testing

The leader in container qualification testing, our dedicated container staff will ensure you comply with FDA requirements. Our testing services include:

- USP <660> glass testing
- USP <661>, <661.1>, <661.2> plastic container testing
- USP <671> container performance testing
- USP <381> elastomeric closure testing
- USP <87> biological reactivity
- Comprehensive EP and JP container testing
- USP Extractable and Leachable Testing

Container Closure Integrity Testing

Pursuant to USP <1207>, our testing methods include:

- ASTM F 2391-05: Helium mass spectrometry
- ASTM F 2338-09: Vacuum decay
- Electrical conductivity/High voltage leak detection (HVLD)
- Laser-based headspace analysis
- Mass extraction

Our Advanced Solutions Also Include:

- X-ray diffraction
- NMR spectroscopy
- Imaging and mapping: Raman mapping, NIR imaging, FTIR mapping, EDS mapping
- Thermal analysis: Differential scanning calorimetry, thermogravimetry, thermal microscopy, solution calorimetry and isothermal microcalorimetry
- Biochemical testing for macromolecules and biochemistry services
- Intellectual property prosecution and litigation support
- Micromeritics and microscopy
- GLP Bioanalytical Testing Supporting Preclincal Testing
- Impurity Identification by high resolution mass spectrometry and/or high resolution accurate mass
- Trace organic compound analysis for Extractables & Leachables/chemical characterization of manufacturing systems (ie Single-Use-Systems), container/closures, and medical devices.
- Toxicological Risk Assessments

AMRI is a global contract research and manufacturing organization that has been working with the life sciences industry to improve patient outcomes and quality of life for more than 25 years.

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