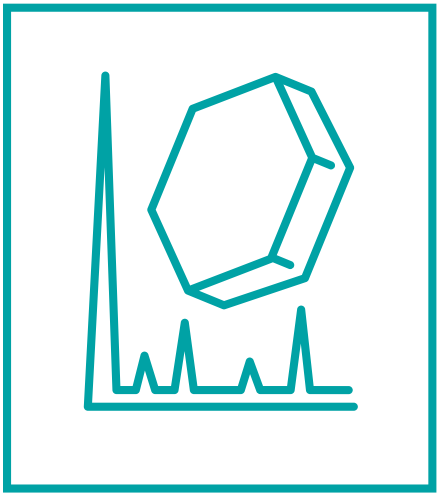
WE'VE GOT DRUG DELIVERY DEVICE TESTING DOWN TO AN EXACT SCIENCE



Analytical and Solid State Services

Speed product development and improve the quality of your compound with solid state chemistry and analytical testing services.

DRUG DELIVERY DEVICE TESTING

Whitehouse Laboratories (now AMRI) performs standard and customized testing for drug delivery devices. Testing can be designed to support all life cycle phases of your combination products from early concept and preclinical testing through final product qualification. The laboratory includes on-site preconditioning necessary for testing according to ISO 11608 — Needle-Based Injection Systems for Medical Use. Additionally, we perform Extractable/Leachable studies to meet the needs of ISO 10993: Part 18 — Chemical Characterization of Materials for Biological Evaluation of Medical Devices, and perform Toxicology Risk Assessments to satisfy ISO 10993: Part 17 — Establishment of allowable limits for leachable substances for Biological Evaluation of Medical Devices.

Staff members with specific areas of expertise are always available to consult with you on your testing needs.

amri

Complex Science. Expert Solutions.

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Syringe Testing

AMRI specializes in syringe testing for a range of applications. We are capable of measuring the force to operate, freedom from air and liquid leakage and many other standards, including:

- ISO 7886 — Sterile, Hypodermic Syringes for Single Use
- ISO 8537 — Sterile Single-Use Syringes, With or Without Needle for Insulin
- ISO 80369 — Small-Bore Connectors for Liquids and Gases in Healthcare Applications —
  Part 7: Connectors for Intravascular or Hypodermic Applications
  Part 20: Common Test Methods

Operating through a dedicated Container Testing Center of Excellence, the entire container testing team actively works with clients to ensure regulatory compliance is always met when it comes to container leak testing.

Dose Delivery Testing

Tech services performs dose delivery testing for devices and combination products according to customer requirements and global standards. The facility has site capabilities to precondition test articles according to ISO 11608.

Relevant standards that address unit dose and dose accuracy:

- ISO 11608 — Needle-Based Injections for Medical Use
- USP <698> — Deliverable Volume
- USP <755> — Minimum Fill
- USP <905> — Uniformity of Dosage Units

Extractable and Leachable Testing

The use of ISO 10993-18 for the Chemical Characterization of Medical Devices has substantially increased in importance by regulatory agencies. In fact, the recent FDA guidance to the Industry on the use of 10993 for biocompatibility, along with both the upcoming changes in ISO 10993-1 and the recent/upcoming changes in the USP, there is a significant importance highlighted to evaluate safety through a risk-based process. The primary source of information to use in the risk assessment is Chemical Characterization data. The actual manner to characterize those chemicals which may leach from a medical device and become available to the patient (directly or indirectly) has not been established specifically.

AMRI provide expert guidance in developing and executing protocols to meet the needs of safety testing through the use of analytical chemistry and biological/toxicological assessment in accordance with:

- ISO 10993 Biological Evaluation of Medical Devices —
  Part 18: Chemical Characterization of Materials
  Part 17: Establishment of Allowable Limits for Leachable Substances

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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