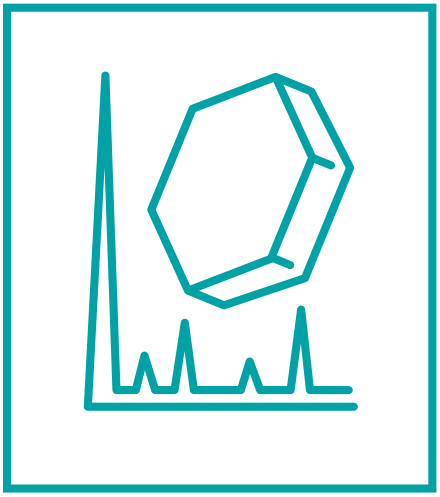
WE'VE GOT MEDICAL DEVICE TESTING DOWN TO AN EXACT SCIENCE



Analytical and Solid State Services

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

MEDICAL DEVICE EFFICACY TESTING

Mechanical and Functional Efficacy Testing

The metrology laboratory is FDA registered and audited, is ISO 17025 and ISTA certified and has the ability to test dimensional force and other mechanical device properties.

Whitehouse Laboratories (now AMRI) provides complete and comprehensive capabilities and expertise for conformity assessment of medical device packages per ISO 11607-2006 — Packaging for Terminally Sterilized Medical Devices — Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems.

ISO 11607 is a fully recognized consensus standard by the FDA and is an essential component of medical device product development. The standard consists of evaluations for stability (ASTM F1980), transportation performance (ASTM D 4169), package seal strength (ASTM F 88) and package seal integrity (ASTM F1929 and ASTM F 2096).

Our equipment includes, but is not limited to:

- Digital micrometers and gauges
- Optical comparators
- Instron universal force testing machines
- Torque meters
- Digital microscopes
- Custom fixtures for complex measurements and components

amri

Complex Science. Expert Solutions.

1-908-403-1318, Mark Stier, VP Global Analytical Services Sales and Business Development
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