

Analytical Testing Capabilities

FOR SUSTAINED-RELEASE AND DRUG-ELUTING TECHNOLOGIES



Full Service Solutions for Every Stage of Drug Product and Medical Device Manufacturing

Trelleborg Medical Solutions leverages in-house analytical testing capabilities to support customers in every phase of the product lifecycle. We conduct material characterization and oversee products to development. To ensure commercial performance, we use Current Good Manufacturing Practice (cGMP) requirements. Our team of experts analyze Active Pharmaceutical Ingredients (API), excipient polymers and other materials to bring game-changing therapies to life.

Ensuring the quality and reliability of pharmaceutical products is paramount. Trelleborg is equipped to support customers that need to transfer an existing test method or develop a new one. We understand the challenges pharmaceutical companies face, and our team of experts is accessible and solutions-oriented. Not every pharmaceutical company has the capacity or

experience to perform its own product release testing. Our analytical scientists and portfolio of capabilities can help. We recognize that each pharmaceutical product is unique, so we've established methods to ensure safety and reliability that fit your product's specific characteristics.

TESTING INSTRUMENTATION

We invest in equipment and instrumentation with our customers in mind. We offer the following tests to support any project.

Raw Materials & Excipient Testing

- Conductivity
- FTIR-ATR
- HPLC/Ultraviolet-Visible
- Spectroscopy/Diode Array Detector (DAD)
- Loss On Drying
- Melting Point Apparatus
- Microscopy
- Polarimetry
- Thin Layer Chromatography (TLC)
- Ultraviolet (UV) Spectroscopy
- Viscosity

Material
Characterization

Product
Development
& Formulation

Product Release Testing

- Burst Testing
- Conductivity
- Dissolution (Apparatus 1, 2)
- Encapsulated Sample Rheometer
- Endotoxin Testing System
- FTIR-ATR
- HPLC/UV/DAD
- Loss On Drying
- Melting Point Apparatus
- Microscopy
- Polarimetry
- Tensile Testing Machine/Universal Testing System
- TLC
- UV Spectroscopy
- Viscosity

Clinical
Manufacturing

Process
Development
& Scale up

Commercial
Manufacturing

ANALYTICAL CAPABILITIES DURING DEVELOPMENT FOR SUSTAINED-RELEASE AND DRUG-ELUTING TECHNOLOGIES

Testing is performed in accordance with the European Pharmacopoeia (EP), United States Pharmacopoeia (USP) and National Formulary (NF) methodologies and monographs. We can also use established customer methods or work to research and identify methods to develop customer products.



STAGE 01

Material Characterization

PHYSICAL PROPERTIES

- Appearance
- pH
- Density
- Viscosity

IDENTITY

- Fourier Transform Infrared (FTIR) & Near-Infrared Absorption Spectroscopy (NIR)
- High-Performance Liquid Chromatography (HPLC) – Multiple Detectors

PURITY/QUALITY

- Absorption Spectroscopy – Multiple Detectors
- Melting Point Determination
- Polarimetry
- Moisture Analysis (Loss on drying)

Raw Material, API and Excipient Testing



STAGE 02

Product Development & Formulation

PERFORMANCE

- Content Assay
- Content Uniformity
- Dissolution - United States Pharmacopoeial Convention (USP) Apparatus 1 & 2

MICROBIOLOGY

- Endotoxin Limulus Amebocyte Lysate (LAL)

PACKAGE INTEGRITY

- Seal Strength Testing (ASTM F88)
- Burst Testing (ASTM F2054)
- Bubble Leak Testing (ASTM F2096)

Test Method Development and Validation, Method Transfer



STAGE 03

Clinical Manufacturing

Product Release Testing



STAGE 04

Process Development & Scale-up



STAGE 05

Commercial Manufacturing

Trelleborg is a world leader in engineered polymer solutions that protect essential applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way.

Trelleborg Medical Solutions partners with the world's leading medical device and biopharmaceutical companies, collaborating from concept to commercialization to bring to market impactful solutions that improve patient quality of life. It leverages decades of design and manufacturing experience, in-depth knowledge of polymer materials to deliver pioneering, engineered solutions for transformative health technologies.

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