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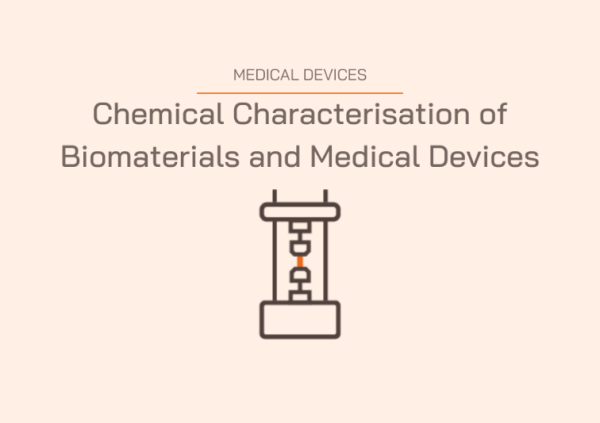
# Chemical Characterisation of Biomaterials and Medical Devices




## What Is Chemical Characterisation of Biomaterials and Medical Devices?

**Material and chemical characterisation** is an essential part of medical device testing and assesses for **safety**, **regulatory compliance**, **performance**, and **reliability**. It is necessary for ensuring for consistency and uniform quality, and for following up on risks that may occur during the lifetime of a medical device. Material and chemical characterisation is included with out other medical device testing services:

- Biocompatibility testing
- Cleaning validation
- Packaging validation
- Stability validation

Applus+ Laboratories provides a **testing service for medical devices under tests described in the ISO 17025 accreditation.** We offer **full product development guidance** to make sure your device is ready for certification on the market, as well as **product and process qualification**, and **Contract Manufacturing Organisation (CMO)**, in order to help you take your product to market.

## How Do We Perform Chemical Characterisation of Biomaterials and Medical Devices Against ISO 10993-18?

At Applus+ Laboratories, we offer comprehensive material and chemical characterisation involving routine analysis of raw materials and final products, contamination

identification, change control monitoring, reverse engineering, and audits. These processes help us identify residual and contamination during the manufacturing process and, depending on the results, can include further work and development with our experts.

## Chemical Characterisation and Quality Control

Chemical characterisation consists of identifying the presence of unexpected and unwanted compounds as well as verifying the quality of a material that might have developed during material reception, manufacturing, cleaning, or sterilisation. At Applus+ Laboratories, we offer the following routine analyses:

- **Residual Solvent Testing**
  Residual solvents come during medical device manufacturing. Their analysis, based on ICH Q3C, is performed using gas chromatography, coupled with mass spectroscopy, allowing for quantification below ppm.
- **Residual Monomer Testing**
  After the polymerisation process, we detect unreacted monomers to avoid potential help risk and toxicity.
- **Residual Hydrogen Peroxide**
  We employ spectrophotometry and titration to ensure safe levels of residual hydrogen peroxide. This is to avoid adverse effects from hydrogen peroxide which can include irritation for patients.

## Identification of Organic and Inorganic Contamination

We detect and identify any unwanted organic or inorganic contaminants in materials used in medical devices. Techniques such as mass spectrometry (MS) and inductively coupled plasma mass spectrometry (ICP-MS) are often used. Contaminants can compromise the safety and effectiveness of medical devices, leading to adverse reactions in patients and failure of the device.

- **Organic Contamination**
  Through the use of gas and liquid chromatography, we identify and quantify the presence of SVOCs, VOCs, and NVOCs, such as cleaning agents, additives, fillers, and polymers. This is achieved using techniques like GC-MS, HS-GC-MS, LC-MS QTOF, and Pyro-GC-MS.
- **Elemental Analysis and Metal Traces**
  We utilise ICP-OES spectrometry to measure and remove elemental impurities in medical devices. The ICH Q3D guideline classifies elemental impurities based on their toxicity, including heavy metals.

## Material Characterisation

Material characterisation involves identifying any changes in the intrinsic properties of materials associated with manufacturing, cleaning, and/or sterilisation. These analyses can also be performed to qualify the material after manufacturing. At Applus+ Laboratories, we offer the following analyses:

- **SEM Microscopy with Elemental Analysis**
  We employ Scanning Electron Microscopy (SEM) which provides high resolution images of the surface morphology of medical device coatings and presence of particles on the surface.This is coupled with elemental analysis that provides the element composition of the structure.
- **Thermomechanical Properties with DSC and DMA**
  Differential scanning calorimetry (DSC) measures the glass transition temperature and melting properties of polymers, which can be useful for controlling polymer batches, ensuring that sterilisation does not affect the crystallinity of the medical device surface, and controlling the polymerisation process as well as measuring the extent of cure of thermoset resins. Dynamic Mechanical Analysis (DMA) evaluates the mechanical properties of materials as they are deformed under periodic stress.
- **Size Exclusion Chromatography (SEC)**
  We perform size exclusion chromatography to provide the molecular weight distribution of polymers, which influences their mechanical and physical properties, affecting the device's performance and durability.
- **Particle Size Characterisation**
  We use diffraction, laser granulometry, and high resolution microscopy to identify particle sizes to control the release rate of coatings on joint implants and the presence of contaminants in medical devices.
- **Surface Analysis**
  We perform surface analysis to analyse the chemical composition of the surface. These analyses are coupled with a comprehensive assessment of the surface state, including topography, wettability, roughness, and wear resistance. These tests allow verification of the quality of the interface and adhesion between coatings and medical devices (to be linked with material and coating sheet).
- **Corrosion Resistance**
  We conduct corrosion resistance testing to assess how materials react under different environmental conditions, including exposure to saline solutions, humidity, and varying temperatures. These tests are crucial to ensure the long-term reliability and safety of medical devices, particularly those with metal components that may be susceptible to corrosion.

## Identification of Origin of Failure or Unmet Specifications

With our advanced equipment capabilities and team of experts in materials and coatings, we track the root cause of failures or unmet specifications. A comprehensive evaluation, along with a survey and audit of the manufacturing process and product life cycle by our dedicated team, helps identify potential sources of non-conformity.

We then conduct chemical and material characterisation to verify and confirm any modifications in the properties of medical devices. This could be material degradation, ageing, or improper operations that may lead to device malfunction.

### Identification of Change in the Product or Process

We support our customers in the case of a change in the product or process, whether through identifying risks associated with the change, exploring alternatives (such as securing supply with a new supplier, considering obsolescence, or improving a product), identifying new manufacturing routes, and/or determining the requirements for new qualifications.

This service can also include conducting a state-of-the-art literature review, identifying new materials, benchmarking, and/or regulatory definition. This is important for detecting and analysing any changes in the product or manufacturing process that could affect the material properties or device performance. We also offer auditing services for material and chemical characterisation.

### Reverse Engineering and Product Development

We perform reverse engineering and deconstruct medical devices to better understand their design and materials. The objective of reverse engineering is often to monitor the composition of a product and anticipate potential obsolescence due to regulatory changes or supply shortages.

This process involves thorough chemical and material analysis, as well as dimensional measurements. Based on this information, potential improvements can be proposed, and the product and process further developed. Guidance on the appropriate choice of materials and processes can be provided during this development phase and later during industrialisation.

## What Are the Benefits of Chemical Characterisation of Biomaterials and Medical Devices?

Material and chemical characterisation, along with being an essential part of our batch testing service, also has a lot of advantages for both ensuring patient safety and for maintaining compliance to medical device related standards. These benefits include this following:

- **Patient Safety**
  Undergoing material and chemical characterisation reduces the adverse effects that patients might experience from the materials coming into contact with bodily fluids or tissues. It greatly reduces the risk of toxicity from harmful materials to maintain the product as safe as possible.

- **Regulatory Compliance**
  Material and chemical characterisation ensures that you follow the stringent standards put in place for medical devices. This regulatory compliance allows you to boost consumer trust knowing that your product has been fully tested.
- **Performance and Reliability**
  Assessing the properties of your product can ensure that the materials used, and the design are reliable and will perform as it should in the range of different stress scenarios it will undergo.
- **Risk Mitigation**
  Material and chemical characterisation can assess potential risks and give advice on design changes in order to properly mitigate these risks. This has a great benefit to patient safety as well as consumer confidence.
- **Market Access**
  Complying with the relevant standards when it comes to medical devices means boosting your market access to a global scale. With the right certifications, you're more likely to operate in more countries.

## Why Choose Applus+ Laboratories for Chemical Characterisation?

Choosing Applus+ Laboratories for your material and chemical characterisation means partnering with a **leader in medical device testing solutions.**

We provide **high-quality, ASTM and ISO-compliant testing services** that ensure the accuracy and reliability of your medical devices. Our comprehensive range of testing capabilities, coupled with our **commitment to client service**, makes us the ideal partner for your batch release testing.

Applus+ Laboratories **strives to be a one-stop shop for medical device testing**, offering a full range of services that can speed up your time to market. We offer:

- Medical device design
- Development of product and process with advice on improvements
- Full lifecycle testing
- Product and process qualification with batch release tests
- Design transfer
- Medical device verification and validation
- In-use cycle product evaluation
- Contract Manufacturing Organisation services

With a **presence in multiple countries**, we can deliver our testing services to customers around the world, ensuring you have access to the best medical device testing no matter where you are.

Let Applus+ Laboratories be your trusted partner for all your medical device testing needs. We can support your projects with our high-quality services and expert guidance.