eurofins | Medical Device Testing



Extractable & Leachable Testing for Medical Devices

As part of the biological evaluation of medical devices compliant to ISO 10993 series, Eurofins BioPharma Product Testing offers Extractable & Leachable testing for medical devices as outlined in ISO 10993 Part 18: Chemical Characterization of Materials.

While analytical methods and concepts are consistent with extractable and leachable testing for containers and closure systems, **quick and affordable** solutions are demanded for the comparison of medical device products after design and material changes, change of raw material production lot, sterilization or ageing. Thus, we have designed the **"GC/HPLC/ICP fingerprint"**, a standardized analytical service for complete chemical characterization of your product.

No matter what the geometry, material or consistency of your medical device product, our experienced scientist will find a way to prepare, extract and analyze it in full compliance **with ISO 10993-18 and ICH Q2(R1) principles**.

Eurofins BioPharma Product Testing is specialized in performing the GC-fingerprint using a GC-FID/MS instrument setup providing both high identification rates within NIST mass spectral library and excellent linear range of the FID-based quantification method. In close collaboration with our established and qualified partners we are able to detect every leachable substance in your product that you should be aware of.

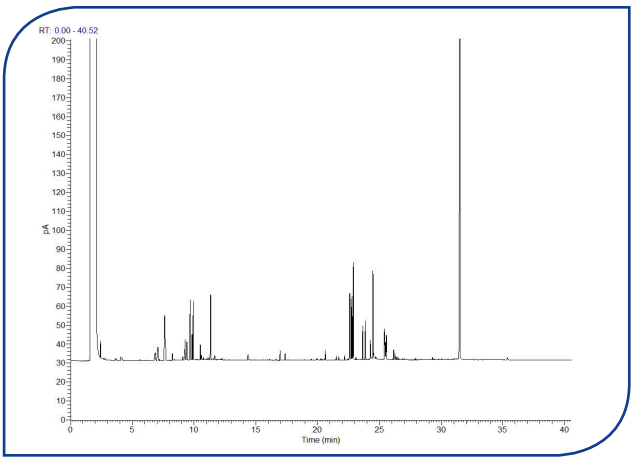
Our multi-disciplinary team of analytical scientists and toxicologist is proficient in researching and concluding expert statements about the detected chemical substances addressing **hazard and risk** that will leave no question unanswered.

Our Equipment

- GC-MS/FID
  (Eurofins BioPharma Product Testing Munich)
- HS GC-MS/FID
  (Eurofins BioPharma Product Testing Munich)
- ICP-OES, -MS
  (Eurofins BioPharma Product Testing Milan)
- HPLC-MS / UV
  (Eurofins BioPharma Product Testing Milan)

Our Analysis Methods

- Method establishment for novel extraction matrices
- Validation in compliance with ISO 10993-18
- State-of-the-art and high throughput
- GLP compliant
- Toxicological risk assessment



Global Services:

Biocompatibility according to ISO 10993
Hemocompatibility Testing
Microbiology
Extractable and Leachable Testing
Evaluation of Reusables
Professional Scientific Services

Our Sites in Germany:

Eurofins BioPharma Product Testing Munich GmbH
Behringstraße 6-8
D-82152 Planegg near Munich

Eurofins Fintelmann & Meyer GMP GmbH
Großmoorbogen 25
D-21079 Hamburg

Phone: +49 89 899 650 0
Email: info-munich@eurofins.com
www.eurofins.com/medical-devices