



WHO WE ARE

GMP
Certification

OFI supports you in the efficient development and approval of your products. We act as a private and independent research and testing institute. Whether medicines are in the development or approval phase or already on the market, we offer you international services in accordance with GMP, EMA and US guidelines.

YOUR EXPERT TEAM

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PHARMA and MEDICAL DEVICES

The independent contract laboratory

GMP certified

Accredited ISO 17025

COMPANY

OFI Technologie & Innovation GmbH
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www.ofi.at/pharma



Quality assurance at highest level



ABOUT US

Testing and consultancy for pharmaceutical products and medical devices are our core competences at OFI. Our range of services includes tests for pharmaceuticals, raw materials and packaging, along with method development and validation for your specific needs. Using a portfolio of animal-free *in-vitro* methods and chemical methods of analysis, we also provide complete biocompatibility testing of medical devices. For the highest level of quality, tests are done under GMP and accreditation.

Whether you are interested in E&L studies or need solutions for your drug approval, OFI experts support you with individual consulting. Referring back to many years of experience in the field of pharmaceuticals and medical devices, OFI provides services for all phases from drug development to approval and on market products.

PRIME TECHNOLOGIES AT OFI

Chromatography

HPLC, GC, HS-GC, IC

Detectors for chromatography

UV/VIS, FLD, MS/MSⁿ, MS-TOF, FID-MS

Spectroscopy

FTIR, SEM/EDX, UV-VIS

Heavy metals analysis

AAS, AES, ICP

Physical Chemical Testing

TOC, refractive index, polarimeter

Container Closure Integrity

Laser-Headspace-CCI, dye immersion, bubble test

Particulate Matters

Light obscuration particle counter



TOP 3 PRODUCTS

01 Extractables & Leachables - Studies (E&L)

OFI has detailed experience in the performance of E&L studies and the field of polymers. We offer you the highest quality and efficiency by using advanced trace analysis to detect, quantify and identify contaminants.

02 Expert Center Particles

In addition to compendial particulate matter testing, OFI runs an expert center to identify the source and cause of impurities. We use highly sophisticated analytical methods, such as FTIR, SEM/EDX and particle counters, to detect, identify and quantify particulate impurities.

03 Drug Release and Raw Material Testing

Whether you need compendial testing, analytical method development, validation or assistance in case of damage, OFI can always provide you with the best consulting and testing to get your product immediately ready for market and authorities.

Method Development and Validation

OFI is specialized in method development for analytical questions of your specific product or raw material and carries out full method validations to the highest quality standards.

Stability assessment studies

OFI carries out stability testing of your products according to ICH under various climatic zones, as well as photo stability testing and stress tests.

Container Closure Integrity (CCI)

OFI provides Laser Headspace Analysis for oxygen ingress, dye immersion testing as well as bubble testing for flexible packaging and testing for penetrability, permeability or for strength of sealed seams for your packaging.

Pharmaceutical packaging

OFI supports you in conformity tests according to Ph.Eur. and USP, Extractables and Leachables studies and Container Closure Integrity tests.

Testing for biocompatibility

For medical devices OFI is focused on biocompatibility tests, skin compatibility tests and chemical characterization, as well as the expert opinion for your product-specific requirements. In our test strategy we rely on validated *in-vitro* tests, to avoid animal testing.

Nitrosamines

Nitrosamines can form from secondary amines and nitrite. To support you in providing a safe and nitrosamine-free product, we test raw materials for nitrite at OFI and perform nitrosamine analysis in finished products according to regulatory requirements.