

From drug development to batch release –
Setting new standards for your business



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From development through approval to already marketed drugs: **ofi** provides international services for your pharmaceutical products in the areas of preclinical development, the preparation of active ingredients and drugs, the development and testing of primary packaging and regulatory affairs. With **ofi** as a fully privately owned, independent and self-funded research institute with GMP certification, your pharmaceuticals are in the best of hands.

Drug development

At **ofi**, we make sure that the development process of your new drugs and pharmaceutical products is as focused and efficient as possible. Your needs are our first priority. Can we give this kind of guarantee? Yes we can, because we do not develop our own products. Rather than that, we act as a fully privately owned, independent and self-funded research and testing institute for the benefit of our customers.

During the preclinical stage, we specialize in resolving chemical, physical and biological issues. Throughout the clinical stages I-III, we focus on analyzing your product and

the biosamples from your studies. We do not conduct in-house animal testing or clinical research. Instead, we collaborate with qualified partner laboratories for in vivo studies. As such, we can be your single source of pharmacokinetic and pharmacological studies.

As a cooperative research institute, we also collaborate with partners at the University of Vienna and at Vienna University of Technology to provide you with cost-efficient synthesis- and galenics-development.

For this **ofi's** quality management process ensures compliance with all relevant regulations.

Top quality guaranteed

For pharmaceutical testing, **ofi** is GMP-certified in accordance with §63 of Austrian Drug Law.

As an accredited testing center, we are certified in accordance with EN ISO 17025. This standard includes all the principles of quality management systems covered by ISO 9001.

We can guarantee top quality standards even beyond GMP and development work, because at **ofi**, tests in all areas are generally covered by an accreditation.

Additionally, **ofi** is authorized to procure toxins and addictive drugs and to handle class I and II biosamples. This allows us to provide you speedy testing of all your products within the corresponding class.





DRUG DEVELOPMENT – CHEMICAL AND PHYSICAL TESTS – STUDIES
MICROBIOLOGICAL TESTS – IN-VITRO TOXICOLOGY – DEVELOPMENT AND
TESTING OF PRIMARY PACKAGING – REGULATORY AFFAIRS – BATCH RELEASE



Chemical and physical tests

Throughout all crucial stages of drug development and release, we conduct tests on your behalf, e.g. identity, assay and purity. We achieve results using a comprehensive range of methods, including but not limited to TLC, GC, GC-MS, HPLC, 2D-HPLC, HPLC-MS/MSⁿ, IC, FT-IR, UV-VIS, AAS, XFA, thermal analysis, rheology or wet-chemical processes.

We develop and validate custom methods of analysis that meet your needs, and use these techniques exclusively throughout your projects. Tests according to Ph.Eur. and USP are conducted routinely. The scope of testing is matched to our customers' needs and constantly expanded. We will be happy to advise you on setting up a suitable testing program.

Biological tests

As a part of pharmaceutical testing, we will also conduct microbiological tests. In-vitro toxicology testing, such as cytotoxicity tests, is performed by our cell culture laboratory.

We conduct studies, such as

- stability studies in multi-functional climatic chambers
- photostability studies
- compatibility studies
- pharmacokinetic analysis
- metabolism studies
- damage assessment, e.g. of particulate impurities caused by manufacturing processes
- structural assessment of unknown impurities
- extractables & leachables studies, sorption studies

A tradition of competence

Reasons to trust *ofi* when it comes to pharmaceutical and medical devices

ofi was founded in 1946 by Austria's chemical industry to serve as a development laboratory. Today our staff of 130 employees works for clients all over the globe. *ofi* operates two sites in Vienna with a total area of 7000m², where our experts engage in life science, chemistry and analytics, surface technology, applied plastics technology, bioenergy and civil engineering. In the healthcare sector, our pharma and medical devices department is ready to be your expert partner. The unit was launched in 1986 to develop and test medical devices. Today, it has grown to be a full-fledged service provider for all your pharmaceutical needs – from development through approval to release.

QUANTUM – Safe packaging for best protection

Immediate contact between plastic packaging material and pharmaceuticals or food, bears a risk: impairment of human health by migration of trace constituents.

To meet this challenge, we have based the goals of our R&D project called QUANTUM on the development of novel screening methods for critical trace constituents of plastics (additives, residual monomers, degradation products, etc.) and to characterize their distribution. QUANTUM aims to incorporate trace analysis, material knowledge and safety assessment.

If you are a manufacturer of plastic products, or you process them, this will enable you to significantly increase their safety and shorten their development cycles.



Testing and development of packaging

To meet your needs, *ofi's* own in-house packaging experts will not only routinely conduct mechanical tests, such as seal strength testing, but also focus on the implementation of container closure integrity tests for various packaging systems.

We will also take on the development of your new application-specific pharmaceutical packaging, ranging from functional to material innovations. Core tests for primary packaging consist of the comprehensive planning and execution of extractables & leachables studies, as well as sorption studies. For your testing needs, be sure to benefit from the long-standing expertise of one of Europe's leading plastics institutes.

At the helm of research and development

Due to our extensive contacts with manufacturers, research institutes and authorities, we are well informed about current trends in R&D. This allows us to align research and development topics with specific needs of our industry customers and derive scientific questions from interests held by sectors, authorities and consumers, on both a national and an international level.

The tradition of progress at *ofi*:

Since 1946, *ofi* has been an expert partner of Austrian and European organizations, and small, medium and large-scale enterprises. *ofi*'s team ensures that our clients' products meet the highest and latest technology standards and supports our customers' innovation efforts by combining research and development, testing, analysis, quality assurance and certification. In addition to being fully privately owned, independent and self-funded, there are a number of reasons why we have become one of the largest testing and research institutes in Austria:

We listen to our clients and cater to their needs. We provide exceptional technical equipment. Our comprehensive expertise and extensive up-to-date knowledge are things we willingly share with our clients and partners. We focus on a limited number of areas. We always provide outstanding flexibility and a wide-reaching partner network. But what really counts is that each of our 130 employees makes it his or her personal goal to help you reach your goal. On your way to success through new ideas, innovations, materials and products, remember that our promise of "progress in good hands" applies to all our main areas of focus.



CONSTRUCTION



PLASTIC PRODUCTS



PHARMA



BIOENERGY



SURFACE TECHNOLOGY



CERTIFICATION

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