



Analytical
services



A close-up, profile view of a young woman with a bright smile, wearing a white lab coat. She is looking down at a notebook and writing with a black pen. The background is a blurred laboratory with various pieces of equipment, including a scale and a beaker containing a pink liquid.

Freshness

We never stop improving our activities; the secret of our success is our open-minded, fresh and positive attitude.

The Highest Quality R&D Services For GMP

We can provide a wide range of services to help in the pharmaceutical development of a new or generic product, starting from pharmaceutical formulation up to preparing an application to obtain a marketing authorization.

Our facilities are situated in Kuopio, Finland, and our laboratory has a GMP Certificate.

- *Formulation development (new and generic)*
- *Technology transfer (e.g. change of a manufacturer)*
- *Stability studies*
- *Analytical chemistry services*
- *Microbiological services*
- *Regulatory affairs*

The core of Medfiles' expertise is its experience in quality control and method development with its wide range of analytical techniques, validation according to current regulatory guidelines, as well as microbiological testing.

We also re-analyze pharmaceutical products for the EU market.

The microbiological testing consists also of comprehensive testing of biological indicators: efficacy of sterilization, population assays, working area hygiene controls with settle plates and surface sampling.

We also can provide you with training and offer consultations on quality auditing, equipment requirements and prerequisites and method validation.

Fairness

We keep our promises. You can trust us and rely on our commitment to co-operation.

Flexibility

We provide the highest quality of work; we are flexible, prompt, and accurate with a professional attitude.

Analytics of powders for inhalation

We have extended our portfolio of analytical services to include comprehensive analytics of powder inhalation products.

Our premises have been expanded and updated and now house a fully equipped and temperature and humidity controlled laboratory for this demanding field of analytical work.

Analytical development and validation during product development as well as method transfer and quality control of powders for inhalation are included in the service.

We can provide stability studies according to ICH guidelines, storage and full analytics including microbiological testing for these products.

Our testing battery includes for example the following Ph.Eur. tests:

- Uniformity of Delivered Dose (e.g. Dosage Unit Sampling Apparatus according to Ph.Eur.)
- Fine Particle Dose and Particle Size Distribution
 - Ph.Eur. apparatus C: Multi-Stage Liquid Impinger, MSLI
 - Ph.Eur. apparatus E: Next Generation Impactor, NGI
- Number of deliveries per inhaler for multidose inhalers

Qualified personnel
Several years of experience in this field

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KUOPIO · HELSINKI · TURKU · TAMPERE · OULU · TARTU · TALLINN · RIGA · VILNIUS

If there is anything you would like to ask us, please, don't hesitate to contact us.

We keep our promises.

Excellence Combined With Speed

Our personnel pride themselves on their experience, commitment, competence and flexibility – they are the foundation of our acknowledged client-oriented service. Our personnel undergo continuous training to ensure that you will be guaranteed services of the highest quality.

We can offer you complete, accurate, up-to-date service to fit the entire life cycle of your product - and our aim is to establish a close, long-term partnership. By outsourcing your pharmaceutical development and laboratory analyses to us, you will be able to focus on your core business, free-up human and fixed capital and simplify your internal administration.