Basic Pharma laboratory services

Ensure **ICH-compliance** of your drug, along with timely production, release and distribution of safe products

To ensure product quality and patient safety, we perform **physical, chemical, and microbiological testing** for you in our contract laboratory.

Our **certified laboratory** offers a plethora of the analytical tests required for starting materials, bulk, and finished products. We are experienced in testing a wide range of compounds and formats and perform tests according to **Ph. Eur. or USP methods.** We are also able to design and validate in-house methods according to customer requirements if no standard method is available. We guarantee timely production, product release and distribution of safe products through our wide range of testing capabilities.

- Release and EU import testing
- Stability testing
- Microbiological testing
- Analytical method development

Release and EU-import testing

One of the most critical aspects of the GMP-based quality system is the final batch release of the drug product before it can be used in a clinical trial or released to the market.

To ensure the product has the required quality, the product and the documentation listed in the Product Specification File (PSF) must be reviewed by an independent Qualified Person (QP).

We can also facilitate the smooth import into Europe of your products manufactured elsewhere, by ensuring they comply with all required regulations and documentation.

Stability testing

We are well-equipped to test the stability of your drug substance or drug product according to ICH standards in our state-of-the-art climate chambers. We have approximately 100 m^2 surface capacity in zone I, II, III, IVa and IVb chambers that control both temperature and humidity.

Testing capabilities

We perform a broad range of tests for drug substances and drug products, including, but not limited to:

- HPLC (UV, DAD, IR and fluorescence detection)
- Droplet size distribution (DSD) and spray pattern analysis
- Cascade impactor
- UV and IR spectroscopy
- Identification testing and limit tests
  - Particle size measurements
  - Pharmacopeial physical techniques

- Tablet testing
  - Dissolution
  - Friability
  - Hardness, disintegration
- Residual moisture
  - Karl Fischer
  - Loss on drying
- Inspection of visual particulate matter
- Container closure integrity

Microbiological testing

Microbiological testing of pharmaceutical substances in a GMP-certified laboratory, both during manufacturing and of the finished product, is essential to ensure compliance. We provide advice and support in a multitude of tests to determine the microbial and endotoxin count of your drug substances and drug products.

Analytical method development

Our team of laboratory experts can call upon their experience in a broad range of analytical methods to develop a tailored method for accurately determining the physical and chemical properties of your drug substance or drug product. We can monitor your product's critical quality attributes throughout the entire development process.

As your partner, we can tailor all services to your specific needs, while respecting all relevant quality guidelines to ensure optimal lead times and efficient product release, supporting an optimal go-to-market process for our customers.

Full service

We have **wide-ranging experience** in drug development, manufacturing, and regulatory affairs. This means we can support your entire process **from product development to commercialization**.

Quality-assured

We are **fully compliant with GMP and ISO 13485:2016 certification** and our Quality Management Systems (QMS) is regularly updated with the latest standards and customer feedback.

Empowered

Our employees apply their expertise to help you find **the optimal path towards success**. They work in a versatile and proactive way, supporting where needed, so you can focus on your other important business goals. Together, we'll identify the **most cost- and time- efficient path towards success**.

Contact us to learn about our partnering opportunities.

Visit **www.basicpharma.nl** to view our other services

Basic Pharma MANUFACTURING

Basic Pharma CONSULTANCY

Basic Pharma GENERIC PRODUCTS

Basic Pharma BIOTECH