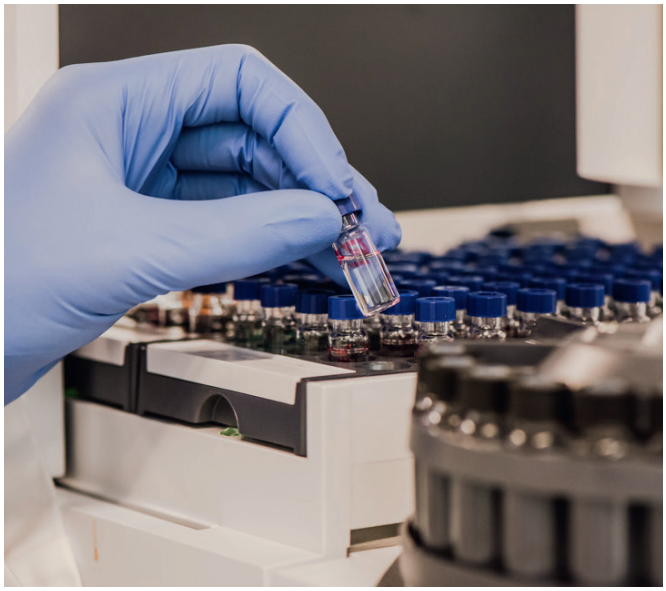
Specialist in chemical analysis

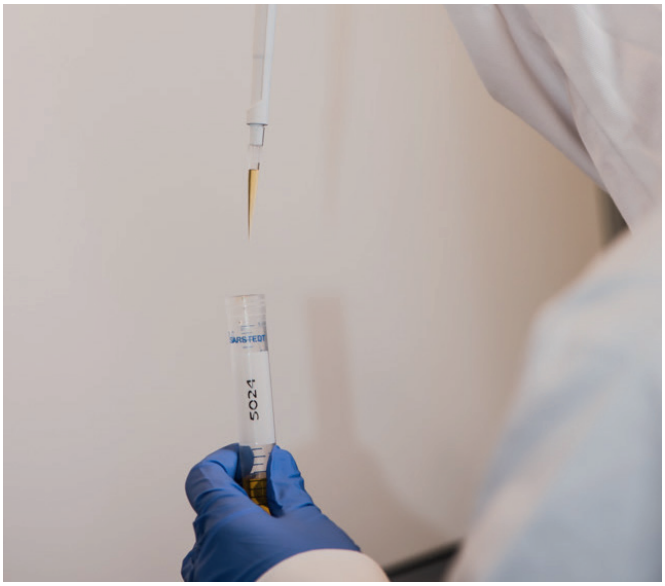
Expert in Pharmaceutical analysis

Introduction
Brightlabs is the laboratory for all your analytical questions. Located in the south of The Netherlands, close to the German and Belgium border, it is our mission to support our customers in their pharmaceutical development projects as well as pharmaceutical QC testing. In finding the correct solution we work in close contact with our customers by Co-Creation, to achieve your end goals in the most efficient manner to maximize your success. Of course Brightlabs has a GMP permit and opiate permits to work on drug substances and drug products.

Services
Brightlabs offers a complete service ranging from physical, chemical and microbiological quality control testing of pharmaceutical products, from raw materials to finished dosage forms. We offer a wide range of support at every stage of your drug development. Our capabilities include; method development and validation, elemental impurity, microbiological testing, stability studies, cleaning validations, quality control testing and much much more.

Method Development:
The development of a robust, selective, stability indicating method to determine compound purity is fundamental to the development of any API. The Brightlabs team has developed hundreds of methods across many different compound classes, including highly complex multi-stereocentre natural product derivatives.
As the development program progresses and more knowledge regarding the process and the compound characteristics is gained, so the supporting analytical methods are developed, and eventually subject to full validation. Brightlabs is experienced in full validation programmes and able to provide data to support the regulatory filing.





Elemental Impurities & Residual testing:
The measurement of very low levels of elemental impurities is a regulatory requirement, described in ICH Q3D and USP232 – 233. Contaminants in APIs (Active Pharmaceutical Ingredients) may be derived from catalysts or from reagents and starting materials. Contaminants in excipients may also be present due to their natural origin. Strict limits apply, and Brightlabs is able to apply state-of-the-art techniques to develop and validate quantitative test methods.

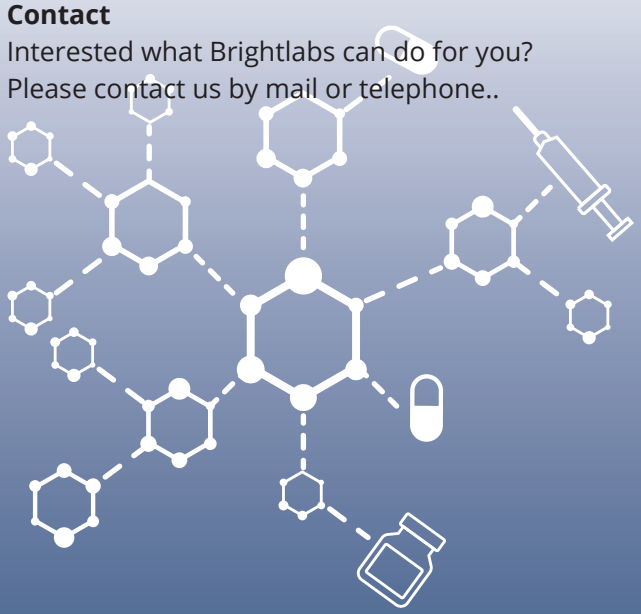
As residual solvents do not provide therapeutic benefit, they should be removed to meet ingredient and product specifications, good manufacturing practices, or other quality-based requirements according USP <467>. Brightlabs is well equipped to measure all classes of residual solvents in low concentrations.

Microbiological Test:
Analytical and microbiological test data are part of Quality Assurance of your production process, release of final products, process validation and stability studies. As part of Quality Assurance also microbiological test methods need to be qualified for its intended use, either by suitability testing or validation of the test method. Brightlabs offers microbiological testing according Ph. Eur. 2.6.12 & 2.6.13.

Stability testing:
Pharmaceutical stability studies are an essential component of the development and lifecycle of pharmaceutical products. The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies in time under the influence of a variety of environmental factors such as temperature, humidity and light. Brightlabs has all the capabilities to setup full compliant stability test to determine the shelf life for the drug substance of drug product and recommended storage conditions.

All studies are performed conform ICH, EP and USP guidelines sufficient for a registration application. This includes storage and all corresponding physical, chemical and bacterial analysis.

Contact
Interested what Brightlabs can do for you?
Please contact us by mail or telephone..



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