BRIGHTLABS
BE RIGHT!

Specialist in Pharmaceutical analysis

Expert in Compendial testing

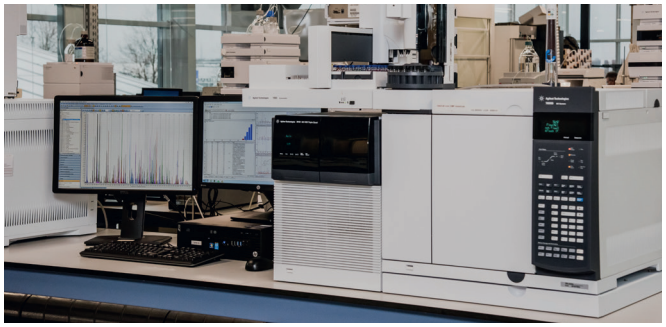
Introduction
Brightlabs is the laboratory for all your analytical questions. Located in the south of The Netherlands, close to the German and Belgium border, it is our mission to support our customers in their pharmaceutical development projects as well as pharmaceutical QC testing. In finding the correct 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.

Compendial testing services
Testing excipients, drug substances and drug products is an requirement and performed in multiple compendia. Brightlabs provides chemical and microbial testing according to the different pharmacopeial monographs.

- European Pharmacopoeia (EP)
- United States Pharmacopeia/ National Formulary (USP/NF)
- British Pharmacopoeia (BP)

Brightlabs also offers the testing on finished drug products and API's, according to different monographs or customer specific requirements. Below a short summary of the test offered without being complete.



Compendial testing services

This includes complete analysis like:

- Physical and physicochemical methods Ph.Eur 2.2 eg:
  - Thin-layer chromatography [2.2.27]
  - Gas chromatography [2.2.28]
  - Liquid chromatography [2.2.29]
  - Inductively coupled plasma-mass spectrometry [2.2.58]
- Identification Ph.Eur 2.3
- Limit tests Ph.Eur 2.4 eg:
  - Fatty Acids [2.4.22]
  - Residual Solvents [2.4.24]
  - Ethylene Oxide and Dioxan [2.4.25]
- Assay Ph.Eur 2.5 eg:
  - Value's [2.5.1 / 2.5.7]
  - Complexometric Titrations [2.5.11]
  - Water: semi-micro determination [2.5.12]
- Biological tests Ph. Eur. 2.6 eg:
  - Microbial enumeration test [2.6.12]
  - Test for specified micro-organisms [2.6.13]

Drug product testing

Besides testing on starting materials and API's, Brightlabs offers a range of analysis as part of the drug product release like:

- Pharmaceutical Technical Procedure Ph. Eur. 2.9 eg:
  - Disintegration [2.9.1]
  - Dissolution testing [2.9.3]
  - Uniformity of Mass [2.9.5]
  - Friability [2.9.7]
  - Resistance of Crushing [2.9.8]

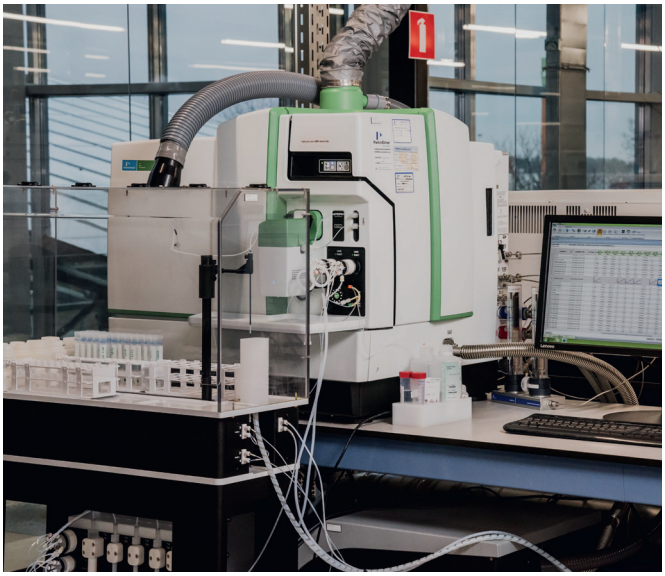
All the mentioned analysis are being performed under Good Manufacturing Practices (GMP) and with full QA support.

Nitrosamine testing

Nowadays testing excipients, API's and final drug products on Nitrosamines is becoming standardized part for the release of many products. Brightlabs has in-house validated methods for screening purposes based on Ph. Eur. 2.5.42, and an extended list of nitrosamines based in EMA and USP list. Using LC-MS/MS and GC-MS/MS methods very low levels of nitrosamines can be detected (i.e. <1ppb levels).

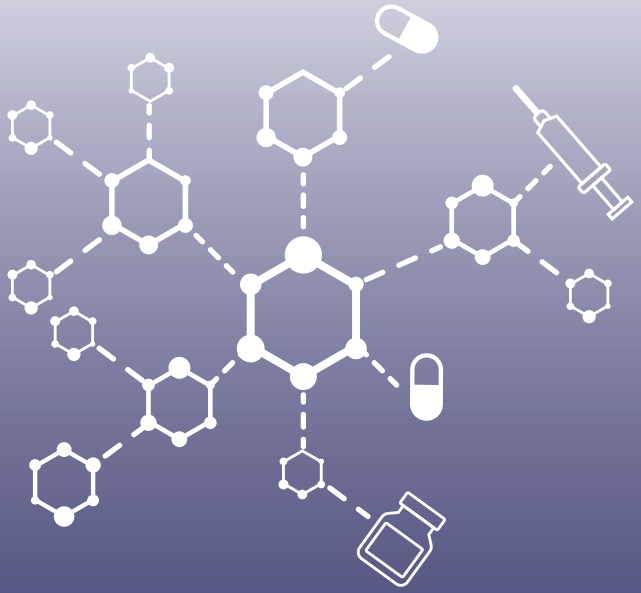
Elemental Impurities

Brightlabs has an in-house validated method for the determination of elemental impurities based on the ICH-Q3D (R1) guidelines. Working with state of the art ICP-MS equipment, securing low level determination for all classes (class 1, 2a, 2b and 3). We have an unique approach which guarantees quick turnaround times at limited cost.



Contact

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



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