



Pharmaceutical GMP laboratory

Chemistry and Microbiology



- more than a lab

Through more than 25 years, DB Lab has served our customers as a contract laboratory focusing on quality, delivery time and the problem solving dialogue.

Staff

The staff is composed of a strong group of laboratory technicians as well as scientists holding a M.Sc. or Ph.D. degree in areas such as microbiology, biochemistry, and analytical chemistry. In collaboration with our customers, we use this wide range of experience and expertise to find the optimal and professional solutions. As a fairly small contract organisation, we consider ourselves fast, flexible, and competent business partners.

Response time

Delivery times are all-important to our customers and, consequently, of highest priority to DB Lab. Procedures to fulfil customer requirements are continuously being optimised – making DB Lab one of the most efficient suppliers of analyses in the market.



GMP authorisation

Quality management is the core of DB Lab. DB Lab is authorised by the Danish Medicines Agency to perform chemical and microbiological analyses in accordance with GMP rules on samples for human and veterinarian purposes. All employees are continuously trained in GMP. Furthermore, we offer FDA compliant testing.



DB Lab is your ideal partner when it comes to

- Chemical and microbiological GMP analyses
- Test of pharmaceutical raw materials, intermediates, and final preparations
- Development of methods and validation, e.g. according to ICH guidelines
- Analytical documentation for registration files
- Method transfer
- Stability monitoring and storage
- Cleaning validation



DB Lab possesses 3,200 m² of which 2,000 m² are laboratory facilities.



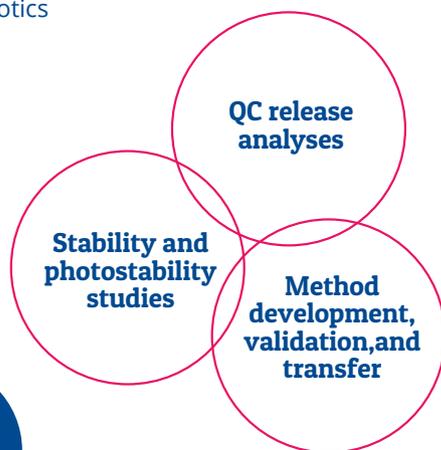
Well-equipped laboratory

- HPLC with detectors such as UV-Vis, DAD, PAD, light-scattering, conductivity, and fluorescence
- UPLC
- LC-MS
- Ion chromatographs
- GC-FID, GC-MS equipped with liquid and headspace autosamplers
- ICP-MS and ICP-OES
- Microwave ovens for sample degradation
- AAS with graphite furnace, flame, and hydride system
- Elemental analyser
- Climate facilities
- Climate chamber for photostability tests
- Disintegration and dissolution equipment
- FT-IR
- Karl Fischer titrators
- UV-Vis spectrophotometers
- Bulk and tapped density equipments
- Sieving system for particle size distribution
- TOC-analyser
- Titrators
- Actuator
- Viscometers
- Kjeldahl apparatus
- Melting point apparatus
- Refractometer
- Osmometer
- Polarimeter
- Hardness tester
- Friability tester
- Laboratory for risk class II microorganisms
- PCR
- Water activity equipment



Examples of our analytical expertise in chemistry

- QC release analyses of pharmaceuticals and raw materials according to Ph. Eur., USP, JP, BP, a.o.
- Method development, optimisation, validation, and method transfer
- Stability and photostability
- Elemental impurities by ICP
- Dissolution profiles
- Cleaning validation
- Trouble shooting
- Control of medical devices
- Analyses of herbal medicinal products
- Control of plastic utensils, e.g. measurements of residual solvents
- Control of packaging materials, e.g. ID of materials by IR
- Elemental analyses
- TOC
- Growth media control, e.g. determination of amino acid composition
- Antibiotics





Examples of our analytical expertise in microbiology

- Microbiological purity of raw material and products according to Ph. Eur., USP, NMKL
- Suitability testing of Ph. Eur. methods
- Strategies to neutralise microbial inhibiting activities of sample
- Method development and validation of bioassays
- Probiotics bacteria; enumeration, identification
- Identification of microorganisms
- Bioassay of antibiotics
- Efficacy of antimicrobial preservation (Challenge test)
- Endotoxin analyses (LAL testing) of pharmaceuticals, raw materials, and water
- Purified water
- Water activity
- Bioburden testing
- Ingress testing
- MIC- and MBC-testing
- Cleaning validation of surfaces and valves
- Growth promotion testing of media preparations



About DB Lab

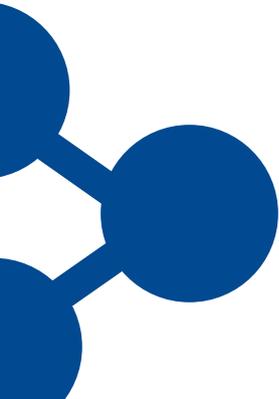
In 1985, DB Lab A/S was founded as Dansk Bioprotein A/S as a center for development of fermentation methods.

The fermentation projects gave DB Lab wide experience within method development and validation.

A know-how that has been elaborated and carried on through decades.

Since 1993, DB Lab has offered analytical services as a highly professional and reliable contract organisation.

In 2003, DB Lab was authorised by Danish Medicines Agency to perform chemical and microbiological GMP analyses.



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