

*Quality Control Services
for the Pharmaceutical Industry*



BIOVIAN

*Your partner in QC services for the
Pharmaceutical and Medical Device industries*

Biovian provides comprehensive analytical solutions to support your drug substance and drug product development, as well as analytical and micro-



biological testing of investigational and commercial drug substances, drug products or medical devices.

Biovian holds GMP-license from EMA to perform quality control of medicinal products. In addition, Biovian contract testing laboratory has been inspected and approved by FDA and is listed on FDA Drug Firm registration. Quality control and contract analysis activities are performed according to the current and audited quality system of Biovian. The focus and extent of the contract manufacturing and analysis services is agreed in customer-specific technical and quality agreements.

Current and harmonized pharmacopoeial methods are utilized in contract analysis, as well as specific methods may be transferred from customer or developed at Biovian if

required. Full validation of analytical methods is also available service for customers.

The expert team at Biovian has extensive knowledge and experience in pharmaceutical method development and validation for raw materials, APIs, finished products and medical devices.

Biovian's facilities are located in Finland, in Turku Science Park with excellent connections through both Turku and Helsinki international airports.

Biovian's 2300m² GMP facilities contain EU grade A, B, C and D class cleanrooms and warehouse under full quality and 24/7 facility monitoring control.

Our experience and know-how in successful development, manufacture and QP release of biopharmaceutical drug substances and drug products will assure that your project is in good hands.

Competent

We live up to our commitments both in terms of quality and timelines. A dedicated project team and project manager will provide an open channel for the customer assuring easy and exact communication throughout all project phases.

Reliable

Our highly skilled teams combined with state-of-the-art equipment enables flexible and efficient pilot production and process development services.

Efficient

Biovia Quality Control Services

Analysis of medicinal products, medical devices, active ingredients, packaging materials and excipients.

Microbiological analysis

- Sterility – membrane filtration and direct inoculation. Ph.Eur. 2.6.1.
- Bacterial endotoxins – gel clot and chromogenic kinetic method. Ph.Eur. 2.6.14.
- Microbial enumeration tests (TAMC and TYMC), including microbial identification. Ph.Eur. 2.6.12.
- Test for specified micro-organisms, Ph.Eur. 2.6.13.
- Efficacy of antimicrobial preservation, Ph.Eur. 5.1.3.

The product-specific validation of microbiological analysis methods – method suitability test, growth promotion test, suitability of the counting method and test for interfering factors.

Physical, physicochemical and pharmaceutical methods, including

- Clarity and degree of opalescence of liquids, Ph.Eur. 2.2.1.

- Degree of coloration of liquids, Ph.Eur. 2.2.2.
- Absorption spectrophotometry, Ph.Eur. 2.2.25.
- Potentiometric determination of pH, Ph.Eur. 2.2.3.
- Osmolality, Ph.Eur. 2.2.35.
- Particulate contamination: visible particles, Ph.Eur. 2.9.20.
- Chromatographical methods

Testing of pharmacopoeial water: microbiological analysis, endotoxins, TOC, nitrates

Stability testing

- controlled temperature and humidity according to ICH guidelines



Microbiological environmental controls

- active air samples
- contact samples
- settling plates

Protein and viral analytics

- development and validation of product-specific analysis methods including general protein chemical analysis, immunoassays and cell based assays. Please contact sales for further details.

Expert services related to contract analysis, including consulting services and 3rd party GMP audit services

The contract analysis services include also testing of small-molecular active ingredients, medical devices and conventional medicinal products.

BIOVIAN

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