



## Microbiological stability - the key to product safety

### Background

Ensuring the microbiological stability of their products is becoming an increasingly complex challenge facing the manufacturers of medicinal products and cosmetics. A more stringent regulatory framework and the rising incidence and prevalence of potentially pathogenic microorganisms often require specialised test procedures and customised solutions.

### Protection and compliance

Microbiological stability is a critical factor when it comes to the quality and safety of cosmetics and dermatological products. After opening, products in multi-dose containers, in particular, are subject to a greater risk of **microbial contamination** due to repeated exposure to germs.

Manufacturers are therefore obliged to ensure that the efficacy of their product preservation systems is assured throughout the entire shelf life. **Preservative challenge tests (PCTs)**, which verify the inhibitory effect against such defined test germs as *E. coli*, *S. aureus* and *P. aeruginosa* in accordance with regulatory requirements and quality standards, such as the pharmacopoeias (Ph. Eur., USP) and ISO standards, have proven to be reliable procedures in this respect. There are also newly emerging, potentially pathogenic microorganisms, which are becoming increasingly important and require an expansion of the test spectrum. The attention of the regulatory authorities is being focused on *Pluralibacter gergoviae* and *Burkholderia cepacia*, in particular, to an increasing extent. These germs can cause serious infections, particularly in children or immunocompromised individuals, and they have already triggered numerous product recalls.

### Testing expertise of the highest standard

With many years of expertise in the microbiological analysis of plant-based products and a comprehensive range of services, PhytoLab is a reliable and efficient partner to help you face these challenges. Our range of

services includes preservative challenge tests (PCTs) in accordance with **Ph. Eur. 5.1.3** and **ISO 11930**, as well as targeted testing for *P. gergoviae* and *B. cepacia*. Routine tests alone or supplemented by tests for specific germs or process validation, PhytoLab adapts every procedure to meet your individual requirements in order to ensure that the microbiological safety of your products is assured. All analyses are carried out under **GMP conditions** and are **accredited** in accordance with **DIN EN ISO/IEC 17025**, ensuring compliance with the highest quality standards and regulatory conformity.

**Contact us to find out more about PhytoLab's microbiological testing services.**

**We would be delighted to advise you. Your contacts at PhytoLab:**



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