



## Microbiological Studies

Eurofins laboratories with a long experience in the field, can advise the customer on the definition and development of protocols for specific studies that will guarantee product safety, particularly with regard to preservation and effectiveness.

Depending on the customer's needs, Eurofins can isolate and identify the contaminating endogenous microorganisms that can affect specific products and use them to verify the effectiveness of the preservative system. In addition to conventional microbiology procedures Eurofins provide molecular biology techniques in compliance with GMP's requirements for quality control of medicinal and biotech products.

All the studies are carried out under GLP, according to internationally recognised methods: EP.BP and USP.ISO, EN... The suitability of microbiological methods for each product is regularly verified before their use and full validation or transfer of the methods is performed if necessary.

### The following test and studies are performed:

- Verification of pharmacopeial microbiological method's suitability
- Microbial identification by DNA sequencing
- Preservative efficacy test (challenge test)
- Bioburden studies
- Sterility testing
- Disinfectant efficacy tests.
- Endotoxins testing (LAL Test)
- Determination of minimum inhibitory concentration and minimum bactericidal concentration
- Set up and validation of NAT methods (Nucleic Acid Amplification Tests).
- Customized microbiological studies.

