

PHARMACEUTICAL MICROBIOLOGY TESTING

Microbiological testing plays an important role in the production of **pharmaceutical drug substances and drug products**.

Pharmaceutical microbiological testing is essential for patient safety as the patients consuming the medicines might already be in a compromised position and easily susceptible to infections.

Eureka pharmaceutical microbiology testing ensures that the raw materials used in drugs match the standard quality requirements before they are processed in the production environment.

Our microbiologists also validate the methods used for testing finished products as well as monitor the quality of air and water from the microbiological perspective.

TESTING SERVICES

We provide pharmaceutical microbiology testing services to manufacturers of both sterile and non-sterile pharmaceutical products and substances. Our laboratories are well equipped and carry out all the required microbiological testing for pharmaceutical industry including-

» **Sterility Testing:**

Sterility testing is an essential microbiology testing requirement that ensures sterile pharmaceuticals, medical equipment and substances are safe for use. We offer two sterility testing methods:

- **Direct Inoculation**
- **Membrane Filtration**

» **Bacterial Endotoxin Testing by LAL Test:**

Limulus Amoebocyte Lysate (LAL) test is performed to check and quantify bacterial endotoxins that are extracted from the products.

» **Microbial Limit Tests:**

Microbial contamination testing is performed for non-sterile products in which harmonised pharmacopoeia or client-supplied methods are used that determine the bioburden within the sample.

» **Total Bacterial Counts:**

Total bacterial count indicates the number of microorganisms present in a sample. The number of microorganisms should not be greater than the specified guide values that are expressed in CFU (colony-forming units) per gram or milliliter.



» **Total Fungal Counts:**

It indicates fungal count present in a sample. Monitoring this is important to know about the fungal contamination in pharmaceuticals.

» **Detection of Pathogens:**

Detection of pathogens in pharmaceuticals finished products and raw materials is important for the safety and well-being of the consumers.

» **Antibiotic Assay:**

This is done to determine the efficiency of antibiotics.

» **Vitamin Assay:**

It is important to determine the potency of vitamins.

» **Assay for Probiotics like Lactobacillus:**

It is used for the total viable count. It is important to ensure that the product is fit for human consumption.

» **Preservative Efficacy Testing:**

This test is performed to check the type and minimum effective concentration of preservative that is required for satisfactory preservation of pharmaceuticals.

» **Area Monitoring:**

We use plate exposures and air sampling methods for environmental monitoring.

» **Microbiological Water Testing:**

Microbiological testing of water is done during different phases of water system validation

» **Total Viable and Non-Viable Particle Count in Large Volume Parenterals**

This is a critical test and is a mandatory pharmacopoeial requirement. Either a microscopic particle count or a light obscuration liquid particle counter is used to perform this test.

» **Development and Validation of Microbiological Testing Methods:**

We have the knowledge and experience to carry out the development and validation of microbiological testing methods.

» **Species Identification of House Organisms:**

Identifying and monitoring indoor microbes is important for health and safety purposes.



As always, **Eureka** is here to support you not only with our **sampling, testing and inspection services**, but also with **expert advice on related topics**.

Please email us for all your upcoming requirements on testing as per above values.