



Center for Technology Transfer and Marketing

CTTM

## MICROBIOLOGICAL TESTING FOR PHARMACEUTICAL PRODUCTS

### DESCRIPTION

IRASM Microbiological laboratory offers a comprehensive range of microbiology services complying with GMP requirements for sterile and non-sterile product testing and facility monitoring.

The laboratory is fully equipped to analyze all the range of pharmaceutical products (sterile or non-sterile) and medical devices. The clean rooms (HEPA-filtered) ensure contamination-free testing.

The bioburden test is used to estimate present total number of viable micro-organisms and the absence of specific pathogens.

The sterility test is used to detect the presence of viable microorganisms.

A critical step is the preparatory testing which validates the product with the method used. This ensures the product has no inhibitory effect on the recovery of microorganisms from the product.

### APPLICATION DOMAINS

We provide **Sterility Testing** on a range of products, including: liquids, solids, parental preparations, ophthalmic & other non-injectable preparations and **Bioburden testing** for any raw materials and finished products.

### MAIN ADVANTAGES

The microbiological tests are performed according to European Pharmacopoeia or other Pharmacopoeia chosen by the customer (USA, Japan). The tests are performed on routine basis or for research purposes. Validation is performed for each product type. The laboratory holds a GMP license issued by Romanian Medicine Agency.



### CONTACT

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### POTENTIAL CUSTOMERS OR COMMERCIAL APPLICATIONS

Pharmaceutical companies seeking for routine or exploratory (R&D) microbiological tests.

### KEYWORDS

**medicinal products, good manufacturing practice, sterility test, bioburden test, facility monitoring**