eurofins | Medical Device Services

Ophthalmic Medical Device Testing

Eurofins Medical Device Testing is a global leader in Ophthalmic medical device testing with expertise in a wide range of products and manufacturing processes to help assess the biological risks of a new device design or process change. Our chemists, toxicologists, and veterinarians can assist with developing an appropriate testing program for assessing the safety of your ophthalmic medical device. From chemical characterisation of degradation products and extractables and leachables testing, to toxicological risk assessments and biological evaluations, Eurofins Medical Device Testing can facilitate the appropriate testing necessary to best support your international regulatory submissions for ophthalmic medical devices.

Choose Eurofins Medical Device Testing to help you:

- Evaluate the biocompatibility of your device
- Assess the impact of a design change or new manufacturing process on your device's safety
- Evaluate new raw materials suppliers
- Consider effects of sterilisation techniques or long-term material stability
- Generate toxicology reports
- Establish biological evaluation plans
- Conduct gap analyses of existing biocompatibility dossiers

Testing Available

Formulation Development

- Ophthalmics
- Solutions
- Lyophilised Formulations
- Injectables

Biological Safety Consulting

- Biological Evaluation Plans
- Biological Evaluation Reports
- Toxicological Risk Assessments
- GAP Analysis
- Peer Review
- Adverse Test Results
- Technical Memorandum

Chemical / Physical Analysis

- Material Characterisation (E&L) - ISO 10993-18
- Material & Product Stability
- Dissolution
- Raw Materials Purity
- Particle Characterisation
- Residual Ethylene Oxide
- Mechanical Testing
- Method Development/Validation
- Pre-form/Formulation Support
- Drug Product Characterisation
- Drug Substance Characterisation
- Drug/Device Combination Support
- Impurity Identification
- Compatibility Studies
- Raw Materials Testing (USP, EP, JP, others)

Biocompatibility Testing

- Cytotoxicity
- Sensitisation
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Subacute/Subchronic/Chronic Toxicity
- Genotoxicity
- Implantation
- Hemocompatibility

Packaging Testing

- Sterile Barrier/Seal Integrity Testing
- Package & Transit Testing
- Shelf-Life/Real-Time & Accelerated Aging
- Label Durability

Microbiology & Sterility Testing

- Sterilisation Validations
- Sterility
- Bioburden
- Endotoxins
- Antimicrobials/Infection Control
- Cleaning & Reprocessing Validations
- Microbial Identification
- Environmental Monitoring

Human Factors

- Human Factors Strategy
- Use-Related Risk Analyses
- Formative Usability Studies
- Human Factors Validation Testing
- Comparative Use Testing
- Labeling Development

Combination Products

- Drug Release and Dissolution
- Chemical Compatibility
- Container & Closure Integrity
- Syringe Testing

Commercial Stability and Release Testing

- HPLC (various detectors)
- Dissolution Apparatus
- Karl Fischer
- Disintegration Apparatus
- UV-VIS/FTIR Spectrophotometers
- Multiple Stability Chambers

Testing Services

Biocompatibility & Toxicology • Cleaning & Reprocessing Validations
Chemical & Physical Analysis • Distribution & Package Integrity
Electrical Safety • Human Factors & Usability • Microbiology & Sterility
Mechanical & Functionality • Viral Safety

Flexible Service Models

Fee For Service (FFS)

Full-Time-Equivalent (FTE)

PSS Insourcing Solutions®

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