

Ciba[®] Expert Services

*Providing Solutions and Consultancy
to the Medical Device Industry*



- R&D Support
- Method Development and Validation
- Quality Control
- Stability Testing
- Reference Material Qualification
- Extractables and Leachables Studies
- Occupational Hygiene Support
- Numetrika[™]: Antimicrobial Efficacy and Adhesion Testing

Expert Services

Value beyond chemistry

Ciba® Expert Services helps you achieve compliance, efficiencies and sustainable success.

Our cGMP and GLP accredited laboratories offer a broad range of testing and consultancy services. We provide reliable, high quality solutions tailored to your needs and delivered to an agreed timetable.

Our specialty is non-routine problem solving by a combination of highly skilled, experienced and motivated staff and extensive state-of-the-art instrumentation including spectroscopic investigations and demanding analytical separations.

R&D Support

- Structural elucidation
- Identification and quantitation of transformation or degradation products
- Characterization of complex formulations
- Failure analysis



Method Development and Validation

- Development of new methods
- Optimization of methods
- Validation according to ICH guidelines
- Transfer of methods and training of personnel



Quality Control

- Release testing of raw materials and final products
- Assay
- Impurities testing, including trace contaminants (nitrosamines, aromatic amines, dioxins, etc.)
- Analysis of residual solvents
- Microbiology

Stability Testing

- Storage according to ICH guidelines
- Analytical testing
- Identification of transformation or degradation products

Reference Material Qualification

- Identity of material
- Purity of material
- Impurities
- Qualification of mixtures

Extractables and Leachables

- Leachability or migration studies
- Identification and quantitation of extractables and leachables
- Determination of the role of additives in polymer formulations
- Recommendations for alternative stabilizers to achieve lower leachability
- Formulation of polymer test samples to evaluate potential leachables



Numetrika™

Antimicrobial efficacy and adhesion testing for medical and other devices and products.


- In vitro testing methodology for evaluating adhesive and antimicrobial performance
- Valuable tool for R&D purposes to determine appropriate concentrations of antimicrobials needed and their homogenous distribution
- Supports quality control measurements for the medical device industry
- Accredited test method for proving antimicrobial and antiadhesive properties of medical devices
- Test reports serve as certificates supporting claims and registration
- A US FDA Device Master File has been submitted

For more information

- Call us in Europe at +41 61 63 68310, in NAFTA at 1-800 431 1900, x2076, or 1-800-CIBA-NOW, x2397
- Visit our website www.cibasc.com/expertservices
- Or speak to your local Ciba representative
- See additional information on Numetrika™ at www.bio-gate.de and www.qualitylabs-bt.de

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Our Knowledge – Your Advantage

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