

Ciba[®] Testing Services

*Leachable & Extractable Studies for the
Global Pharmaceutical Industry*



- *Do you know if the stabilization package has been changed in the plastic and rubber used to fabricate the components of your medical devices?*
- *Are the stabilizers you use transforming or degrading over time?*
- *Are the additives, stabilizers, and colorants used in your medical packaging the components that leach out?*
- *Don't wait until Quality Control testing to learn the answers to these questions!*

Ciba® Testing Services specializes in analytical support for the pharmaceutical, food, medical packaging and devices industries.

With more than 50 years of hands-on experience supporting the polymer and packaging industries, Ciba® Testing Services provides analytical support for:

- Regulatory issues, occupational hygiene or environmental compliance
- Impurity profiling
- Complex formulation identification
- Extractables and leachables determination

Ciba's full-service, analytical GLP/GMP and material testing laboratories are well equipped to characterize a variety of materials and determine their critical physical and chemical properties.

Ciba® Testing Services offers technical development and problem solving expertise in a number of industries including plastics, automotive, agriculture, construction & pipes, home & fabric care, inks & graphics, lubricants, packaging, paints & coatings, paper, personal care, textile & fibers and water treatment.

Extractables Studies for Medical Devices and Medical Packaging

- Characterization of the polymer systems
- Complete, quantitative additives and stabilizer screen
- Quick and decisive identifications of extractables including transformation or degradation products
- Determine the role of each additive in polymer formulations. Make recommendations for alternative stabilizers for greater compatibility with the package or device to achieve lower leachability.

Leachables and Migration Studies

- Conduct leachability or migration studies on polymeric medical devices or packaging
- Provide complete identification of leachables
- Formulate polymer test samples as a screening tool to evaluate potential leachables under end use conditions
- Ability to work with C¹⁴ labeled compounds
- Liquid Scintillation Counter and many other advanced analytical techniques



For more information

- Call us at 1 800 431-1900, x2892 or x2076
- Visit our website www.cibasc.com/expertservices
- Or speak to your local Ciba representative

Ciba® Expert Services
Our Knowledge – Your Advantage