

# Extractables and Leachables

## Studies for the Global Pharmaceutical Industry



We are specialized in analytical support for the pharmaceutical, food, medical device and packaging industries. With several years of hands-on experience supporting the polymer and packaging industries, we provide analytical support for:

- Extractables and leachables determination
- Impurity profiling
- Complex formulation identification

Intertek'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.

We offer 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.



We can provide both routine and highly specialized services to determine and characterize extractables and leachables, including comprehensive capabilities for analytical method development and validation



### 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 C<sup>14</sup> labeled compounds
- Liquid Scintillation Counter and many other advanced analytical techniques

Intertek Expert Services conducts a wide range of studies to determine extractables and leachables that play a critical role in the characterization of many pharmaceutical and related healthcare products.

### Extractables and Leachables Services

- Developing and validating methods (HPLC, GC, ICP) for controlled extractables from pharmaceutical containers, closures and devices
- Identification of extractables using GC/MS and LC/MS/MS
- Modifying specific controlled extractables methods for routine E/L testing
- Validation of routine methods for product release
- Leachables profiles
- Validation of leachables methods for use in storage and stability programs
- E/L testing for pharmaceutical packaging and compatibility

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