

Quantex Laboratories offers full analytical support for extractables and leachables testing. Extractables and leachables are chemicals that can be released or migrate from product or packaging components, such as rubber, plastic, and glass under various conditions of normal use, that have the potential to contaminate a drug. We have comprehensive expertise developing and validating methods for the determination of extractables and leachables in various drug products.

Our scientists leverage their knowledge and experience in developing and validating methods to identify extractables and leachables. We can assist you in the development of an appropriate leachables and extractables program which is tailored to suit your specific needs and timelines. This includes performing material characterization studies as well as extractables & leachables method development and validation. Our analytical instrumentation, which includes GC-MS, LC-MS, LC-MS/MS, HPLC and many others, provides us with the tools necessary to characterize, identify, and quantify the extractables and leachables in drug products and medical devices.

Our service capabilities include:

- Controlled Extraction Studies
- Migration studies
- Extractable profiling and identification
- Extractables and leachables method development and validation
- Extractables and leachables “routine” testing

Sources of Extractables and Leachables include:

- Plastics
- Coatings
- Elastomers.
- Antioxidants
- Stabilizers
- Accelerants
- Metal oxides
- Vulcanizing agents

Methods employed include:

- Metals by AAS, ICP and ICP-MS
- Phthalates by GC-MS
- Nitrosamines by LC-MS
- Volatile organic compounds & residual solvents by Headspace GC-MS
- Polycyclic aromatics by HPLC and GC-MS

For more information on our capabilities please contact our Business Development group at (732) 248-3335, extension 405.



Our State-of-the-Art Instrumentation includes:

- HPLC: (UV-Vis, PDA, electrochemical, ELSD)
- LC-MS with APCI & ESI
- LC-MS/MS with APCI & ESI
- GC-MS: direct injection, headspace capability with EI and CI ionization source
- HRGC-HRMS
- Flame AA
- GFAA
- ICP & ICP-MS
- Mercury analyzer
- IC



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