



EXTRACTABLES AND LEACHABLES

A Pharmaceutical Development Company.

INDUSTRY UPDATE

AVOID CONTAMINATION EARLY IN THE DRUG DEVELOPMENT PROCESS

Investigate the potentially harmful effects of your container/closure system on your drug product by partnering with Irvine Pharmaceutical Services. Irvine has more than 12 years of combined experience with polymers, metals and an array of pharmaceutical products to assist in identifying the threat of contamination to your drug products. Let Irvine leverage this expertise in a thorough examination of impurities in your drug formulation.

Irvine's Expertise Supports Full Analysis of Extractables and Leachables for:

- pMDI
- Nasal products
- LDPE ampoules
- PVC blister packs
- Injectables
- Medical devices
- IV bags
- Ophthalmics
- And many more container/closure systems

Extractables and Leachables – Vital to your FDA Application Regulations make Extractables and Leachables studies an essential part of your development process. Our team of skilled scientists is highly experienced in developing and validating new methodologies in support of various container/closure systems.

Our Comprehensive Services

- 3-Phase Systematic Approach
 - Profile extraction studies
 - Control extraction studies
 - Leachables studies
- Routine container/closure testing
- Formulation compatibility and stability
- Identification, isolation and quantification of Extractables and Leachables

State-of-the-Art Instrumentation

- GC/MS and/or GC-FID (including headspace analysis)
- LC/MS/MS (diode array or single wavelength detector)
- ICP

We invite you to visit us, audit our laboratories, discover our insight, and learn more about our passionate commitment to partnering excellence. To learn more, please visit www.irvinepharma.com or call 877-445-6554.



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