Nitto Avecia Pharma Services

extractables/LEACHABLES

Avoid introduction of foreign materials in the drug development process.

Investigate the potentially harmful effects of your container/closure system on your drug product by partnering with Nitto Avecia Pharma Services. Our team of structural scientists have over 10 years of experience with polymers, elemental impurities, and an array of pharmaceutical products to assist in identifying the threat of contamination to your drug products. Let Avecia Pharma leverage this expertise in a thorough examination of impurities in your drug formulation.

EXPERTISE SUPPORTING A RANGE OF PRODUCTS AND DELIVERY SYSTEMS

- pMDI
- Nasal products
- LDPE ampoules
- PVC blister packs
- Injectables
- Medical devices
- IV bags
- Ophthalmics

OUR COMPREHENSIVE SERVICES

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.

- Three-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 or LC/UV
- ICP/MS
- UPLC/MS/MS
- QTOF

Contact us at 877-445-6554 or visit www.aveciapharma.com.