Chemical Services: Extractables & Leachables

Extractables are chemical species that migrate from a product or packaging component under aggresive exposure or storage conditions such as high temperature, long duration & contact with solvents.

Leachables are chemical species that migrate from the product or packaging components under normal conditions of exposure or storage.

ARDL offers comprehensive support for extractables and leachables studies, with years of experience in identifying and quantifying organic and inorganic components in a wide variety of products, including: polymers, plastics, metals, pharmaceuticals and other matrices.

Good Manufacturing Practices

21CFR211.94(a)(b)

- **Drug product container and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality or purity beyond the official or established requirements.**

- **Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.**

Techniques

Analytical techniques involved in extactables and leachables studies include:
- Gravimetric and Colorimetric Analysis
- Inorganic Species by ICP/MS Analysis
- OrganicSpecies by GC/FID, GC/MS, Pyro-GC/MS, HPLC, LC/MS/MS
- pH
- Spectroscopy (UV/VIS, FTIR)

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Rubber. Plastic. Latex.

Extractables & Leachables
(cont.)

Extraction Studies per 21 CFR *(§177.2600, §177.1520 and many more...)*

USP 381: Elastomeric Closures

- Extraction
  - IPA (30 min @ Reflux Temperature)
  - Purified Water (4 Hours @ 121°C)
  - Drug Vehicle (30 min @ Reflux Temperature)
- Turbidity
- Heavy Metals
- Reducing Agents
- pH Change
- Total Extractables (Gravimetry, mg)

USP 661: PET and PETG

- Extraction (10 days @ 49°C)
  - Purified Water,
  - 25% Alcohol
  - 50% Alcohol
  - n-Heptane
- Total Terephthaloyl Moieties
  (Spectrophotometry, ppm)
- EG (Spectrophotometry, ppm)

USP 661: Physicochemical (PE and PP)

- Extraction
- Nonvolatile Residue
- Residue on Ignition
- Heavy Metals
- Buffering Capacity

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