ARDL

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

# Pharmaceutical Services: A cGMP Laboratory US Pharmacopeia Testing

All plastic materials and components used to package pharmaceuticals, biologics, dietary supplements and medical devices in the United States must, by federal law, meet the standards set by the United States Pharmacopeia (USP). USP standards are also recognized and used in more than 130 countries. In fact, many of these countries require the use of these standards to assure the quality of medicines and similar products.

The ingredients used in your polymer compounds and production process must also meet the requirements in the Code of Federal Regulations or be determined acceptable substances for their intended use by the FDA. ARDL is an independent, FDA compliant testing laboratory that helps regulatory agencies and manufacturers of containers and closures ensure that they meet the high standards of the USP and the FDA.

**ARDL is able to perform a number of testing procedures to certify that your products are of the appropriate quality, integrity, consistency, purity and potency.**

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## USP ‹381›: Elastomeric Closures for Injections

- Absorbance
- Acidity or Alkalinity
- Ammonium
- Extraction
  - Drug Vehicle
  - IPA
  - Purified Water
- Determination of Color
- Extractable Zinc
- Fragmentation
- Heavy Metals
- Identity Test
- Opalescence
- Penetrability
- pH Change
- Reducing Substances
- Self-Sealing Capacity
- Total Extractables
- Turbidity
- Volatile Sulfides

## USP ‹661›: Containers – Plastics

- Buffering Capacity
- Colorant Extraction (PET and PETG)
- Differential Scanning Calorimetry
- Ethylene Glycol in PET and PETG Extracts
- Extraction (10 days @ 49°C)
  - 25% Alcohol
  - 50% Alcohol
  - Purified Water
  - n-Heptane
- Extractions and Heavy Metals for PET and PETG
- Heavy Metals
- Nonvolatile Residue
- Physicochemical Test Extract
- Infrared Spectroscopy Identity Test
- Residue on Ignition
- Total Terephthaloyl Moieties in PET and PETG

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