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Identification of Potential Extractables & Leachables - Medistri

🚀 Identification of Potential Extractables & Leachables

GC/MS Analysis (also called Gas Chromatography/ Mass Spectrometry) is an analytical process that utilises the capabilities of Mass Spectrometry and Gas Chromatography in order to determine the chemical compounds within a sample.

The identification of potential extractables and leachables (E&L) using GC/MS (Gas Chromatography/Mass Spectrometry) is a critical process in ensuring the safety and compliance of Pharmaceuticals and Medical Devices that come into contact with humans.

1. **Safety:** Ensures products are free from harmful chemicals that can migrate from packaging or manufacturing processes.

2. **Regulatory Compliance:** Required by FDA, EMA, and other agencies to ensure product safety and approval.

3. **Quality Assurance:** Maintains product stability, efficacy, and shelf-life by controlling chemical contaminants.

A systematic approach based on analytical techniques such as Gas Chromatography/Mass Spectrometry (GC/MS) is used to identify potential Extractables & Leachables.

Samples are subjected to extraction using solvents that simulate the conditions under which the product is stored or used. Extracted samples are then analyzed using GC/MS, where compounds are separated based on their volatility and affinity on a chromatographic column, and subsequently detected and identified based on their mass spectra.

This process allows for the precise identification and quantification of trace levels of chemicals that could migrate from packaging materials, containers, or manufacturing equipment into the product. The use of GC/MS ensures high sensitivity and specificity in identifying potential extractables (released under extraction conditions) and leachables (migrated into the product), supporting regulatory compliance and safeguarding product quality and consumer safety.

Our laboratory works according to ISO 17025 (current version) and is accredited since 2008 by the Swiss Accreditation Service (SAS). All testing can be performed according to European or US pharmacopeias.

ISO 17025, an international standard for testing and calibration laboratories, ensures the accuracy and reliability of methods used to identify potential extractables and leachables (E&L). It mandates rigorous Quality Management Systems (QMS), technical competence in analytical methods, and calibrated equipment.

These requirements support precise E&L testing, crucial for detecting trace contaminants that may migrate into products from packaging or manufacturing processes.

ISO 17025 certifies Medistri Laboratory as meeting high standards of quality, complying with regulations, and effectively assuring consumer safety.

🎯 To learn more about Medistri's Identification of Potential Extractables & Leachables, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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