LabAnalysis
HIGH QUALITY CONTROLS

Delivering scientific excellence

LEACHABLE & EXTRACTABLE

During drug production phase or during drug storage phase, by direct or indirect contact between the packaging material and the active ingredient or the formulated product, numerous contaminants can be released from the materials.

These molecules are **Extractables** or **Leachables** and their determination is one of the regulatory requirements for patient safety.

> **Extractables** are all compounds that can be extracted from materials if placed in contact with solvents or simulants under controlled time and temperature conditions, but worse than the conditions of normal use. Extractables can potentially migrate into the drug.
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> Contrarly, **Leachables** are all compounds that migrate into the pharmaceutical product from any material because of direct or indirect contact between the material and the product itself during the production phase or during the storage of the pharmaceutical product.

LabAnalysis, with its consolidated experience, acquired from the delivery of hundreds of Extractables and Leachables studies, and with a state-of-the-art analytical instrumentation, will perform **any type of analysis on a very wide type of materials** (primary and secondary packaging, dispensing and dosing systems, industrial components, filtering systems, etc.) and **pharmaceutical products** (active pharmaceutical ingredients and formulated products).

In order to perform a forced degradation study, LabAnalysis guarantees the use of the **best chromatographic and structural characterization technologies** (HPLC-UV-MS systems for the determination of non-volatile compounds, HS-GC-MS systems for the determination of volatile compounds, GC-MS systems for the determination of semi-volatile compounds, ICP-MS systems for the determination of metals, IC systems for the determination of ionic compounds).

LabAnalysis will share with the Client the technical approach of the Extractable and Leachable studies by drafting a **Study Protocol** containing information regarding the purpose of the activity, the analytical methods, the stress and processing conditions of the samples, the processing and presentation results, regulatory references. At the end of the experimental activity, LabAnalysis will draft a related **Study Report** containing all the experimental information, the numerical data obtained, the mass balances, the chromatographic traces and the considerations on the results.

Please don't hesitate to contact us for further information about the services you need. Our technical division will help you find the right solution for your analytical enquiries.

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