Custom Extractables and Leachables Solutions

Conducting Extractables and Leachables (E&L) studies is a complex, multi-layered process which requires comprehensive analysis of both finished pharmaceutical products and their packaging in order to identify any potentially harmful compounds or drug impurities that could impact the product and be administered to patients unintentionally.

E&L studies are conducted for a variety of reasons, foremost of which are regulatory requirements that mandate that they be performed to ensure that products and packaging are free of harmful extractable and leachable compounds, both organic and inorganic in nature. Scientific research, augmented by case studies over time illustrate why it is necessary to perform these studies as well as the repercussions that may arise if they are not.

Our dedicated team of experts employ definitive analytical techniques, providing qualitative and quantitative analysis of all extractable and leachable compounds which could impact pharmaceutical products, medical devices and related packaging. A qualitative risk-based approach not only allows for the identification of extractables and leachables, but also provides a determination of the potential issues they pose to patients.

Our E&L studies are customized to a particular product and/or packaging, with your needs at the forefront. Our process involves a multiple step E&L investigation designed to examine every attribute of both product and packaging in order to amass the necessary information to carry out a thorough E&L study:

- Critical Assessment
- Extractables Study
- Data Evaluation and Interpretation
- Extractable and Leachable Correlation Study
- Toxicological Risk Assessment
- Leachables Study

Intertek's decades of experience and industry expertise in providing in-depth identification and analysis of extractables and leachables provides solutions for of a wide variety of products, including:

Pharmaceutical Finished Products

In accordance with Good Manufacturing Practice (GMP), USP and ISO-10993 requirements, Intertek offers E&L studies for products such as pre-filled syringes, single-use manufacturing systems and disposable medical equipment. Through our controlled extractable studies, we develop and validate methods for controlled extractables from pharmaceutical containers, closures and devices. The use of CG/MS, GC-MS/MS and LC/MS/MS (including unit resolution and HRAM instruments) enables our experts to quickly and accurately identify extractables. Intertek’s sophisticated sample preparation capability ensures effective reduction of matrix related interferences resulting in high quality data packages.

Medical Devices

Specific devices such as implantable medical devices deserve special scrutiny in regard to extractable and leachables testing given that they are implanted within the patient, providing critical, in some cases life-sustaining services. These types of products must be demonstrated to be free of impurities that could pose risk to the health of patients.

Through our extractable studies for medical devices and medical packaging, we provide fast and accurate identification of extractables, including transformation or degradation products. Furthermore, the characterization of polymer systems encompasses the determination of additives’ roles in the formulation of polymers. This process allows our experts to provide objective insight into alternative stabilizers of greater suitability with the device or packaging, and lower the potential of leachability of harmful compounds.
Expertise in Extractables and Leachables Studies

Pharmaceutical Consumer Products
The market for pharmaceutical consumer products consists of many devices, such as pressurized metered dose inhalers, nasal sprays and others which fall into the category of orally inhaled and nasal drug products (OINDP). These have the highest level of potential interaction between the packaging material and the drug product based on their route of administration. As innocuous as these types of devices may appear, it must be taken into consideration that they are constructed from a wide variety of materials - including metals and rubbers - along with dedicated additives and process materials.

An in-depth analysis of not only the device, but each of its components is required to examine the potential for extractables and leachables at all levels, including all compounds that could be released from the container closure system, such as additives and additive breakdown products.

Comprehensive Analytical Techniques
To carry out E&L studies for a wide range of medical and pharmaceutical products, Intertek experts utilize a variety of mass spectrometry based hyphenated techniques including GC-MS, GC-MS/MS HRAM LC-MS/MS and ICP-MS. Our experts deploy solventless extraction methods such as Solid Phase Microextraction (SPME), Dynamic Head Space (DHS) and Stir Bar Sorptive Extraction (Twister). Inductively coupled plasma atomic emission spectroscopy (ICP-AES) and Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) are used for elemental screening and quantitative determination of extractable and leachable compounds.

Intertek also uses laser ablation ICP-MS to evaluate the metal composition and elemental impurities of highly resistant materials such stainless steel, titanium, PTFE, UHMWPE.

With such tools at their disposal, the Intertek team is able to provide custom solutions for E&L studies, selecting the approach which is best suited to a particular product or packaging material, and providing optimal results.

The Intertek Solution
Our worldwide team of experts are not limited to solely performing the required studies, but will interpret the results in order to develop an in-depth understanding of the risks for extractables and leachables in your products and packaging. Our GMP-compliant laboratories in the US and Switzerland provide global support for customers, meeting your needs for extractable and leachable studies and exceeding your expectations.
Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 40,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers’ operations and supply chains.

*Bringing quality and safety to life*