EXTRACTABLES AND LEACHABLES SERVICES

Intertek Pharmaceutical Services

intertek
Total Quality. Assured.

Custom Extractables and Leachables Solutions

Studies tailored to a particular product and/or packaging to meet your specific needs

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 or concerning compounds or drug impurities that could impact the product and be non-intentionally administered to patients.

Those in the medical and pharmaceutical industries may conduct E&L studies 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. Science, as well as examples from the past, also demonstrate why it is necessary to perform these studies and the repercussions which can occur from failing to do so.

Our global team of experts employs state-of-the-art and comprehensive analytical techniques, providing qualitative and quantitative analysis of 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 risk they pose to patients. E&L studies are customized to a particular product and/or packaging and are tailored to your specific needs.

Our process involves a four step E&L investigation designed to examine every aspect of product and packaging in order to have 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 a wide variety of products, including pharmaceutical finished products, medical devices, and pharmaceutical consumer products.

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, allows our experts to quickly and accurately identify extractables. Intertek's special state-of-the-art sample preparation capability ensures effective reduction of matrix related interferences resulting in high quality data packages, higher level of regulatory compliance and lower detection limits.

Expertise in Extractables and Leachables Studies

Helping you to interpret results to develop an in-depth understanding of the risks for E&L in your products and packaging

Medical Devices

Medical devices, particularly implantable medical devices, deserve special scrutiny when it comes to extractable and leachable testing given that they are placed inside the patient, providing critical, in some cases life-saving or life-sustaining services. These types of products must be demonstrated to be free of impurities that could pose considerable 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 provides for the determination of the role each additive plays in the formulation of polymers. This process brings the ability to make recommendations of alternative stabilizers which could provide greater compatibility with the device or packaging, and lower the level of leachability of harmful compounds.

Pharmaceutical Consumer Products

The pharmaceutical consumer products market consists of many devices such as pressurized metered dose inhalers, nasal sprays, and others which are orally inhaled and nasal drug products (OINDP), which have the highest level of potential interaction between the packaging material and the drug product based on their route of administration. As simple as these types of devices may seem on the surface, it must be taken into account that they are constructed from a wide variety of materials (e.g. metals, rubbers, etc.), along with dedicated additives and process materials. Given this, thus 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 GC-MS, LC-MS/MS and ICP-MS. These high-end hyphenated systems produce more reliable data the first time. The data packages provided are generated by both GC-HRAM and LC-HRAM based instrumentation.

Intertek uses 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 as stainless steel, titanium, PTFE, and UHMWPE.

Having these tools at their disposal allows the Intertek team to provide custom solutions for E&L studies, choosing the approach that is best suited to a particular product or packaging material, and providing optimal results.

The Intertek Solution

Our worldwide team of experts bring their knowledge into not only performing the studies, but also in assisting you in interpreting the results 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 convenience for customers worldwide to meet all of your needs for extractable and leachable studies.

About Intertek

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 42,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

Did You Know?

- Intertek developed a patented extraction vessel to evaluate anesthetic devices and device parts.
- Intertek is using Twister® based extraction methods and GC-MS/MS technology to evaluate leachable components at the pg/mL or sub pg/mL level.
- Intertek is one of the first laboratories to implement HRAM based detection methods for both GC- and LC platforms.
- Our system's performance qualifications are testing the systems under very rigorous conditions using different mixtures at a pg/mL concentration level.

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