



Extractables and Leachables



Assessment of Extractables and Leachables is an essential part of drug product development and is a regulatory requirement to ensure patient safety. Studies to understand the interactions between the drug product and the packaging/closures, medical devices and manufacturing equipment are often complex and involved. At RSSL we provide a bespoke risk based study to ensure a pragmatic approach that meets the requirements of the regulators.

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USP <1663> and <1664> provide guidance for the design of extractables and leachables studies, but do not set out methodology of specifications. Our analytical capabilities and technical expertise in performing these studies ensure that we provide the support you require to meet the regulatory requirements.

Our bespoke risk based study approach involves:

1. Profiling the extractables from the materials in contact with your drug product using our generic screening methods with:
 - a. Selection of suitable extraction media
 - b. Analysis for organic and inorganic extractables
2. Stability storage of products
3. Method optimisation (if required) and validation for quantification of significant leachables in the specific drug product matrix
4. Analysis of product for organic and inorganic leachables over a number of timepoints
5. Identification of impurities above the safety threshold
6. Toxicological support for evaluation of leachables of concern

RSSL can provide analytical support during all stages of this process. We have performed controlled extractables and leachables studies on a wide variety of containers and closures using a range of analytical technologies (LC-MS, GC-MS, ICP-MS), and our specialists' expertise and experience means you can rely on us to successfully set up and manage your project.

**Contact us to find out more about our expertise
and how we can support you:**

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