EXTRACTABLES & LEACHABLES STUDIES

SOLUTIONS TAILORED TO YOUR SPECIFIC PROJECT NEEDS

Neopharm Labs offers extractables & leachables studies designed by our Scientists to meet unique and diverse project requirements. Our R&D team is composed of pharmaceutical industry experts who conduct impurity profiling of drug products, from early stage isolation, purification and characterization to the investigation of foreign substances in commercialized products.

- Our GMP compliant laboratory focuses only on pharmaceutical industry requirements
- We design E&L studies protocols customized to you project that respect USP <1663> and <1664>
- Our R&D experts support the E&L study itself and special investigations

E&L GENERAL METHODS

- Volatile substances analysed by Headspace injection on GC/MS
- Semi-Volatile substances analysed by Direct injection on GC/MS
- Non-Volatile substances analysed by LC/MS (QTOF) using negative and positive modes
- Elemental Impurities analysed by ICP-MS
- Free Halides analysed by IC (Dionex) using conductivity detection (performed only on demand)

EXTRACTABLES ASSESSMENT

1. **Detailed protocol:** The Safety Concern Threshold (SCT) and Threshold of Toxicological Concern (TTC) are calculated for your specific finished product based on the Safety Concern Threshold (SCT) discussed for each product based on its intended use.
2. **Custom stress treatment:** The container closure system to be tested will be treated with one or more extraction types (ex. accelerated product use, aggressive conditions, etc.) using an extraction medium stressed under specific conditions (temperature and time). The type of extraction chosen is documented in the protocol after discussion with the client.
3. **Extensive analysis:** The extracts are analysed with the above mentioned methods for their specific goals.
4. **Data interpretation:** The results are then analysed and reported within the method's limits. For each substances detected above the AET, a Tentative Structure is determined using commercially available databases as well as an in-house library.
5. **Confirmation of the structures:** If available, reference standards are then ordered in order to confirm the identities and concentrations of the substances detected.
6. **Comprehensive reporting:** Results are then summarised in a comprehensive report that gives a list of the extractables structures found above the AET with their proposed structures and estimated concentrations.

LEACHABLES ASSESSMENT

1. **Direct extractable-leachable correlation:** When an expired finished product is available, the leachables assessment is performed directly in parallel to the extractables profiling. This allows a direct extractable-leachable correlation in-between the aggressive conditions used in the extractables study and the leachables found in the end product. In this case, the leachables assessment is directly included in the extractables study report.
2. **Accelerated product use:** When no expired finished product is available, we can stress an available finished product in accelerated conditions in order to establish a risk assessment for leachables in this container closure system.
3. **Monitoring in a stability study:** Develop and validate methods in order to monitor all the potential leachables previously identified in the extractables study using long-term stability conditions through all the shelf life of the finished product.

SPECIAL INVESTIGATIONS

Neopharm also performs special investigations based on E&L studies in some particular cases, such as:

- client/patient complaint or change in the appearance of a product
- unknown peaks increasing through a stability study

These studies are specifically designed for each problematic based on the deep expertise of our Specialists using the mass spectrometry platform available in our R&D Department. An investigation report is then generated to propose a structure and name for the unknown substances identified with an identification certainty level and, if possible, a semi-quantitation of these substances.

We also have the capacity to isolate and purify any foreign substances (process impurity, degradation product, leachable, etc.) found in your drug substances or drug products. A small amount of the purified material is used for a complete characterization of the impurity (accurate mass measurement, mass spectrum, NMR). The remaining quantity can be used to validate this impurity in your related substances analytical method within our GMP laboratory approved by both FDA and Health Canada authorities.

ABOUT NEOPHARM LABS

Neopharm Labs is a leading analytical testing laboratory serving the global pharmaceutical industry. We combine innovation with exceptional quality and service levels powered by a dedicated team of experts to fulfill the requirements and evolving business demands of our customers. Our wide portfolio of analytical services enables us to offer a full range of services at every stage of the drug development and commercialization cycle. With sites in the US and Canada, our state-of-the-art laboratories are licensed by the FDA and Health Canada. We provide support to Canadian, U.S. and European customers leveraging our participation in Global MRA's.

To discuss how we can help with your extractables and leachables testing, contact me directly:

MATHIEU FOURNIER, Director, R&D and Scientific Affairs | mfournier@neopharmlabs.com
T. 1-844-435-8864 ext. 309