

Your Challenges Require Smart Solutions.



Extractables & Leachables Testing

A Service for Manufacturers of

- Bio- and Pharmaceutical Products
- Medical Devices
- Packaging Materials for Pharmaceutical Products

GBA PHARMA provides complete services for Extractables & Leachables from consulting to extractable studies, expert reports on substances with toxicological concerns, validation of analytical methods to migration and sorption studies all in one hand.

Benefits from Our Support

- Identify potential chemicals that may migrate from packaging materials or the production process into your product
- Qualify and optimize packaging materials and production processes
- Maintain product quality and safety
- Generate data for a toxicology and risk assessment
- Meet current regulatory requirements

Further information about our service portfolio can be found at www.gba-pharma.com





Extractables & Leachables Testing

Our Approach in Extractables Testing

- Research and evaluation of product data and information incl. gap analysis
- Justify the choice of plastic material(s)
- Development of a study concept
- Extractables study

This study is conducted to understand which substances are contained in a specific material and have the potential to migrate into the drug product. Different suitable solvents and multiple analytical techniques are used for the determination of lead compounds.

- Toxicology and risk assessment
- Identification of extractables above AET (analytical evaluation threshold)
- Assay

Method development or optimization of an analytical procedure for trace analysis (sample preparation and method parameters) for inorganic and organic compounds.

Method validation typically based on customers requirements (e.g. ICH guidelines: selectivity, specificity, precision, accuracy, linearity, range, LOD, LOQ, robustness)



All methods used for extractables and leachables studies will be validated according to customer's needs, typically based on guideline ICH Q2(R1).

Our Approach in Leachables Testing

- Leachables Study (Migration Study)

Release of substances (leachables) from plastic components into the content of the container under conditions which reproduce those of the intended use.

Further studies can be performed on request such as

- Leachables Study (Sorption Study)

Bonding of a solute to a packaging component as a physicochemical process that is related to the properties of the packaging material and the chemical properties of the active substance or other soluble substances in the preparation.

