

Know what's inside.



## Extractables & Leachables Testing

A Service for Manufacturers of

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

provided by Phytos, LAT, and LPU

**Experts for Analytical Solutions**



Phytos



LPU

## Our Approach in Extractables Testing

- **Justify the choice of plastic material(s)**
- **Development of a study concept**
- **Extractable study**

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

- **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 extractable and leachable studies will be validated according to customer's needs, typically based on guideline ICH Q2(R1).**

## Our Approach in Leachables Testing

- **Leachable 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.



## 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

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If you are interested in our services, please contact:

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Further information about our service portfolio can be found at [www.gba-group.de](http://www.gba-group.de)

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