GVK BIO
Accelerating R&D

Extractables and Leachables Solutions

The testing and assessment of Extractable and Leachable substances in finished drugs and their packaging material is extremely important to mitigate the patient safety risk associated with harmful product contact materials. Extractables and leachables can lead to potential contaminants in the final product and may impact product efficacy, color, taste, smell, and its pH. Other effects may involve inactivation of the active ingredient and increase in the carcinogenic risk associated with the drug.

Extractable and Leachable studies are therefore a crucial component for the safe release of a drug into humans, and help identify impurities that migrate into the final product from contact surfaces encountered during drug manufacture and storage.

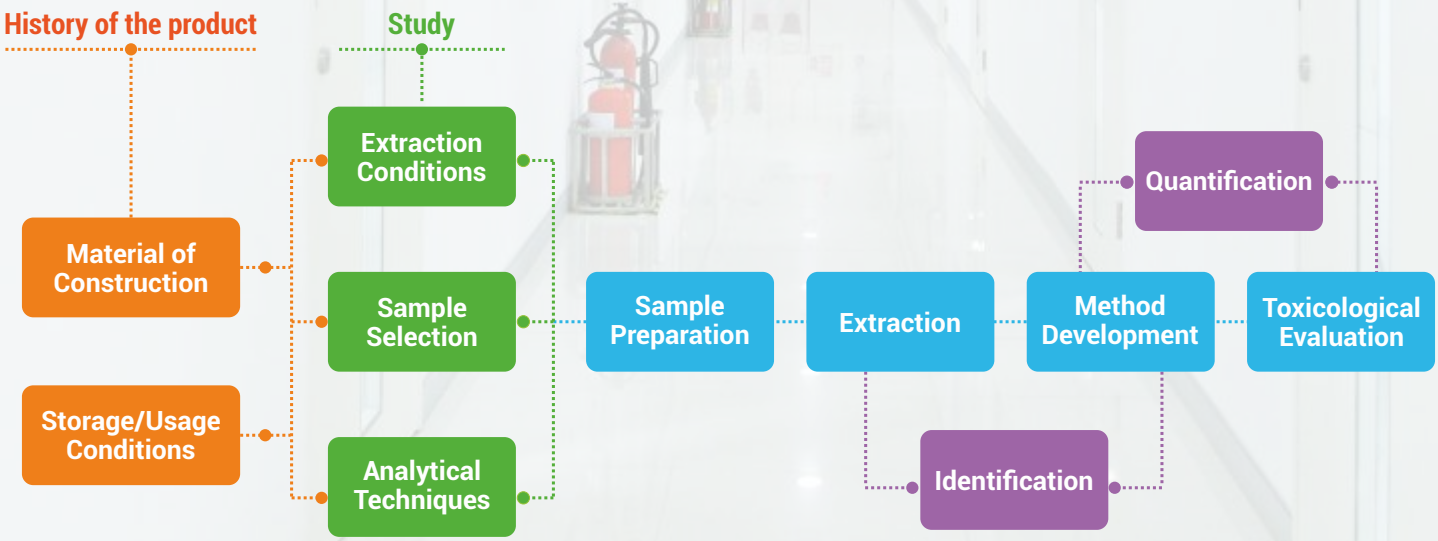
Conducting Extractables and Leachables studies is a complex, multi-step process. At GVK BIO, we carry out a comprehensive Extractable and Leachable testing program in accordance with global regulatory recommendations and guidelines. These studies can either follow standard procedures or can be tailored to meet specific customer requirements. Supported by a world-class infrastructure, our analytical experts assess your needs, develop protocols and then drive method development, method validation and stability testing, enabling you for successful and safe product launch.

Extractables and Leachables Study Design

Our study design aims at examining every aspect of the drug product and packaging in accordance with regulatory requirements. These include:

1. Study of product contact material and safety risk assessment
2. Extractables and Leachables study and analysis
3. Toxicological evaluation and validation
4. Risk assessment and toxicological report
5. Quantitative and qualitative analysis of E&Ls

Stages in an Extractables and Leachables Study



RISK ASSESSMENT & STUDY DESIGN

EXTRACTABLES STUDY

DATA ASSESSMENT

LEACHABLES METHOD DEVELOPMENT

LEACHABLES VALIDATION

LEACHABLES SHELF LIFE STUDY

Analytical Techniques

Analytical Technique	Extractable/Leachable	Example
LCMS	Non-volatile organic compounds	Nitrosamines, Antioxidants, Oligomers
GCMS (Direct injection)	Semi-volatile organic compounds	PAHs , Plasticizers, Preservatives, Siloxanes
GCMS (Headspace)	Volatile organic compounds	Processing solvents, Adhesives, Siloxanes
ICP-MS	Toxic elements	Arsenic, Lead, Chromium

Why to Perform E&L Studies

Critical examples from the past - pharmaceutical packaging area (MDI)	Polyaromatic hydrocarbons (PAHs), mercapto-benzothiazole and N-nitrosamines; (prefilled syringes) tungsten case & photoinitiators
Critical examples from the past - food packaging area	ITX and other printing compounds and N-Nitrosamines
Scientific reasons	Additives and process chemicals are small molecules, some pharmaceutical formulations are quite good solvents for such extractables
To avoid surprises	Degradation products of polymeric matrix or additives. Unknown compounds from manufacturing of the packaging ("NIAS") and contaminants. Compounds migrating from printing and adhesives into the drug products
Regulatory Guidelines	**USP, EP, FDA, EMEA**

Leading Small Molecule **CRDO**

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