GVS Cibatech Pvt. Ltd.

GVS CIBATECH
सुरक्षा, संवर्धन

Extractables & Leachables Studies

Qualitative and quantitative investigations which ensure that a pharmaceutical packaging or contact material is safe with regard to chemical components and which does not negatively influence the drug.

Solutions for Safe Pharmaceutical Packaging

Why GVS Cibatech

Our extended expertise in Polymer, Packaging and Pharma places us in a unique position to offer effective solutions in dealing with Formulations & Packaging interactions.

Experienced team that has performed more than 100 EL studies on various dosage forms and drug delivery systems.

End to End solution right from study design to tox evaluation, consulting and training support.

www.cibatech.com

Instrumentation

TDS – GC/MS with olfactory port
LC/MS MS
HPLC
ICP-MS
DSC
FTIR

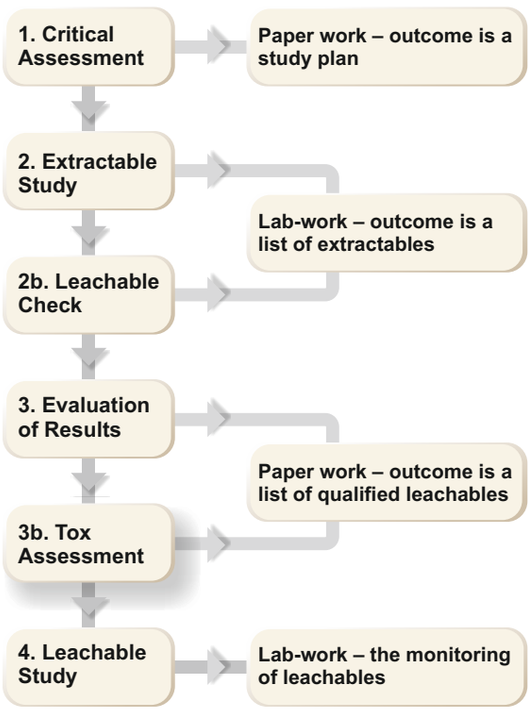
Material Qualification Studies

USP <661> Containers—Plastics / Physical Tests
USP <381> Elastomer closures for injections
USP <87> Biological reactivity tests, In vitro
USP <88> Biological reactivity tests, in Vivo

- Metered dose inhalers (MDIs) and other dosing and inhalation systems
- Infusion bags, vials for injection, pre-filled syringes, and catheter systems
- Blister materials, and containers for orally applied medicines
- Stoppers (rubber / non-rubber material, with / without membranes)
- Laminated systems / adhesives
- Printings / inks and ink formulations
- Process materials like Tubings, Filters, vessels etc.

Strategy for Extractable/Leachables

*An E&L investigation is **not one single study**, it is at least divided in **4 subsequent major steps**:*



Our Deliverables

- Extractable & Leachable studies for Pharmaceutical Packaging Systems, Drug Products as per PQRI, USP and other relevant guidelines.
- Decisive Identification of extractables including transformational and degradation products.
- Toxicological evaluation of leachables, consulting and training support.
- Alternative approach for E/L (including desktop risk assessment) for low risk dosage forms – Solid/Liquid Orals, Topicals etc.
- Chemical Characterization Studies for Medical Devices as per ISO 10993 – Part 17 and 18.
- Consulting and support on Glass Delamination Studies.
- Additive analysis for Polymers, Rubbers and other materials.

For more information

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