



EXTRACTABLES & LEACHABLES

225+ E & L STUDIES WITHOUT
ANY REGULATORY QUERIES

In the current scenario where E & L studies have become mandatory to meet the safety requirements of medicines and medical devices, Daicel offers the most comprehensive Studies for various portfolio products and a broad range of packaging materials.

Our team also adopts communication and reporting channels through a project management system to match customer specific requirements. We have a team of scientists who are committed to provide the best solutions which meet the needs of pharmaceutical companies.

Daicel offers

Vast experience of understanding different formulations, plan and design E & L studies in accordance with current regulatory guidelines

In house state of the art facility for isolation and synthesis of impurities observed above AET in the leachable studies

Validated methods for both Simulation studies and Leachables studies

Risk based approach to E & L Study Design keeping the end goal in mind

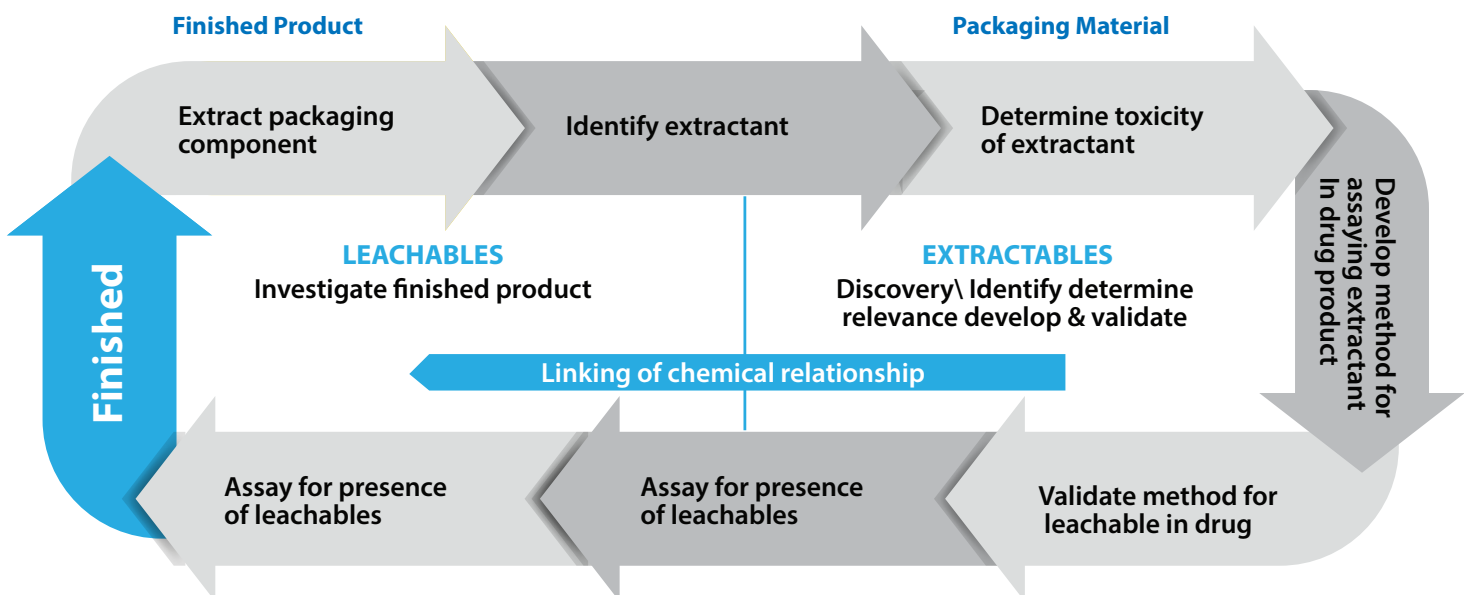
Quick TAT's

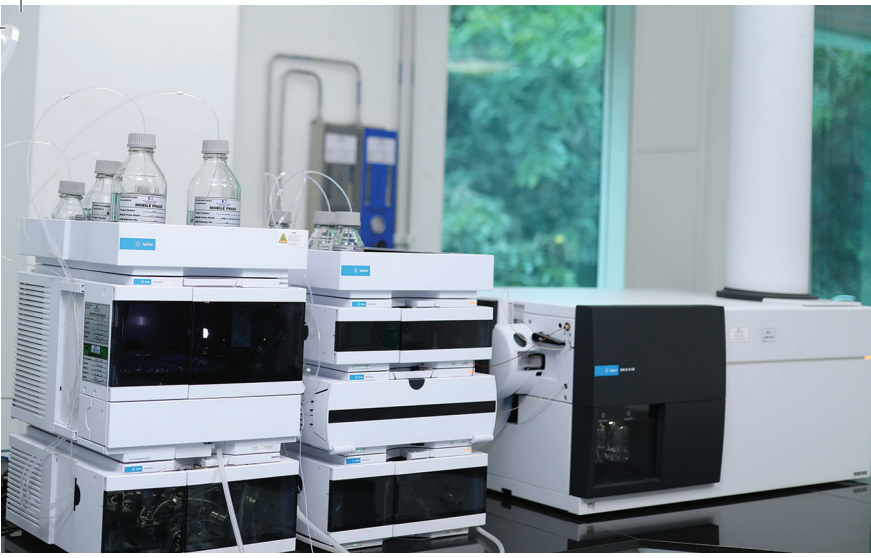
Extractable & Leachables - Quantitative Studies

Why EL testing : Safety and risk to humans

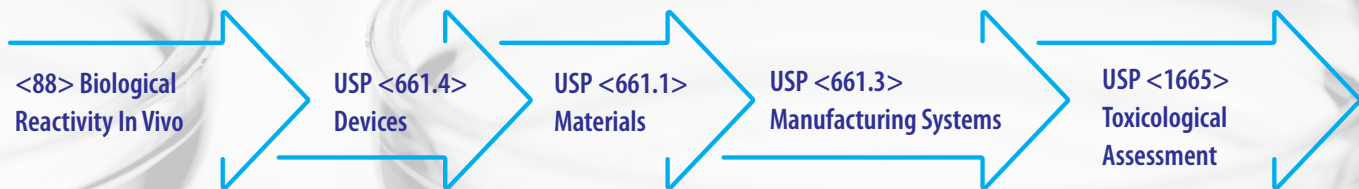
Risk associated with administration route	Risk of CCS interacting with drug product		
	High	Medium	Low
Highest	<ul style="list-style-type: none"> Inhalation aerosols and solutions Injections and injectable suspensions 	<ul style="list-style-type: none"> Sterile powders and powders for injection Inhalation powders 	
High	<ul style="list-style-type: none"> Ophthalmic solutions and suspensions Transdermal ointments and patches Nasal aerosols and sprays 		
Low	<ul style="list-style-type: none"> Topical solutions and suspensions Topical and lingual aerosols Oral solutions and suspensions 	<ul style="list-style-type: none"> Topical powders Oral Powders 	<ul style="list-style-type: none"> Oral tablets and oral capsules

Relationship cycle



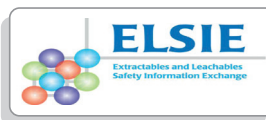


USP Chapters dealing with E & L



Equipped with GC-MS/MS, LC-MS/MS, HRMS, ICP-MS and IC

We ensure compliance with



Key Daicel Capabilities like

Packaging Materials

Polycarbonate

Rubber stoppers (Chlorobutyl, Brombutyl)

Cyclic Olefin copolymer

Polyvinyl chloride

Low density polyethylene (LDPE)

High density polyethylene (HDPE)

Glass vials

Closures

Plungers

Drug Products

The "4I's": Inhalants, Injectables, Infusions, Implantable

OINDPs (Ophthalmic, pMDI, DPI, Nasal Sprays...)

Dermal and Topical Applications

Bio disposables / Single Use Systems

Vaccines

Medical Devices

Label/Ink Migration

Parenterals

Peptides/Biologics/Complex Injectables

Feeding Tubes etc



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