

SPECIALITY STUDIES

Iron Carbohydrate Complex Drugs

- » Dialysable iron under physiologically relevant conditions. The tests can be performed with in vitro haemodialysis system
- » The catalytic bleomycin assay of spiked human serum samples
- » Spectrophotometric measurement of Fe reduction, or other methods that are validated for accuracy and precision (Labile iron determination – Kinetic Study)

IVBE Studies

- » Equivalence studies from Simple to Complex drugs
- » Support Bioequivalence filing by conducting Dissolution studies, Equilibrium & Kinetic binding studies and Bioassays (including enzymatic assays) for different drugs like, Ferric citrate, Cholestyramine, Sevelamer Carbonate, etc.
 - Sucralfate (BSA binding study, Bile salts equilibrium study/kinetic binding study, Pepsin assay) as per new FDA guidance



Dissolution

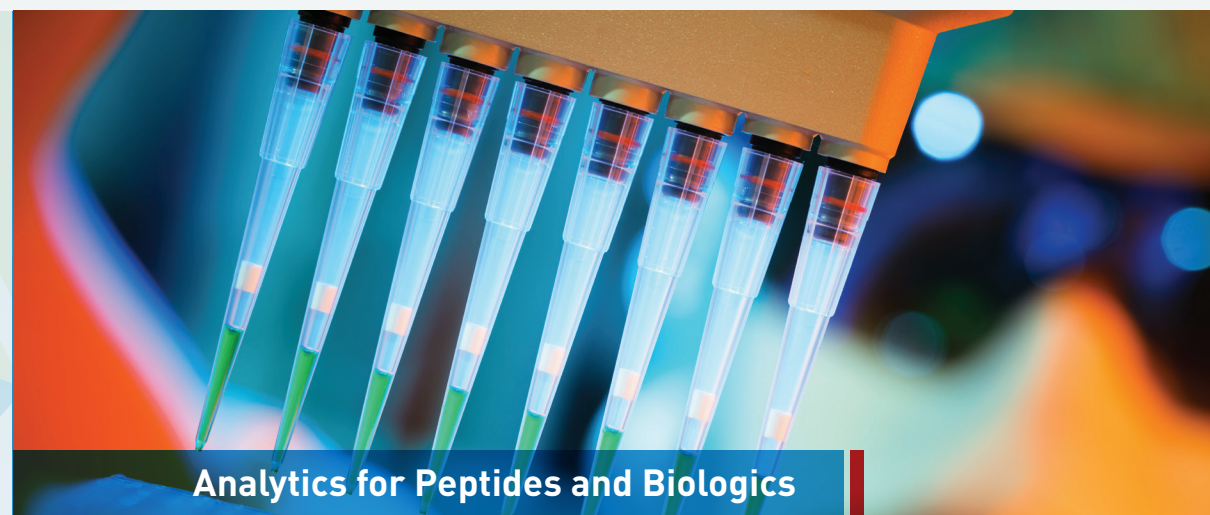
HPLC

ICP-MS

IC



Successful FDA audits in 2016, 2019 and 2023



Analytics for Peptides and Biologics

- » Physico chemical characterization of Peptides and Biologics
- » Higher Order Structural characterization of Peptides
- » Lot release assays for Peptides and Biologics
- » Bioidentity assays for Peptides
- » Bioassays for Peptides and Biologics
- » Neutralizing antibody assays for Biologics
- » Biosimilarity assessment studies
- » Residuals Testing by ELISA
 - Protein A
 - Benzonase
 - Bovine Serum Albumin (BSA)
 - Host Cell Protein (HCP)
 - Human Serum Albumin (HSA)
 - Insulin
 - Long-IGF3

Bioassay

- » Bioidentity methods as per USP monograph and general chapters
- » Custom based Bioassays



Analytical Services from DAICEL



Daicel Chiral Technologies (India) Pvt. Ltd.
 Survey No.542/2, IKP Knowledge Park, Turkapally
 Shamirpet Mandal, Medchal-Malkajgiri District
 Hyderabad-500101, Telangana, India.
 T: +91 84186 60700
 F: +91 84186 60730
 E: chiral@chiral.daicel.com
www.daicelpharmaservices.com



www.daicelpharmaservices.com

US-FDA audited Facility

- » METHOD DEVELOPMENT
- » METHOD VALIDATION
- » BATCH RELEASE TESTING
- » METHOD VERIFICATION
- » METHOD TRANSFER



OFFERINGS

Type of Analytical Services

Dedicated Lab for the Analysis of Cytotoxic and High Potent Drugs

- » Dissolution studies including DPDM
- » Non-Carryover Studies
- » Genotoxic Impurities Quantification
- » Ion Chromatography Studies (Counter Ions)
- » Forced Degradation Studies
- » Assay methods by HPLC/UPLC
- » Residual Solvents Methods by GC-HS
- » Enantiomeric Purity Methods by Chiral HPLC
- » Related Substances Methods by HPLC/UPLC
- » Bio Equivalence Studies
- » Stability Studies for APIs and Drug Products
- » Extratable & Leachable Studies
- » Microbiology
- » Biopharmaceutical Services
- » Peptide Services
- » IVBE Studies
- » Release Testing

GMP TRACE ANALYSIS



Genotoxic Impurity Quantification Studies: GC-HS-MS/MS & LC-MS/MS

- » Quantification of Potential Genotoxic Impurities in APIs & Drug products at ppm level
- » Non-carryover Studies in APIs
- » Batch release testing

Nitrosamine impurities analysis and NDSRI analysis

Elemental Impurity Studies: ICP-MS

- » Risk assessment studies as per ICH Q3D/USP <232> & USP <233>
 - API • Oral • Parenteral • Creaml • Inhalation Products
- » Regulatory filings support (IND/DMF/ANDA)
 - Method Development • Method Validation • Batch Analysis
- » Single method solution for 24 elements screening in APIs/Drug Products
 - Semi Quantitative • Quantitative

EXTRACTABLE & LEACHABLE STUDIES



Packing 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

- » Inhalants/MD
- » OINDPs (pMDI, DPI, Nasal Sprays...)
- » Dermal and Topical Applications
- » Implantables
- » Bio disposables / Single Use Systems
- » Infusions
- » Medical Devices
- » Vaccines
- » Label/Ink Migration
- » Parenteral/Injectables
- » Peptides/Biologics/Complex Injectables
- » Feeding Tubes etc.

Also offers Glass Delamination Studies

KEY ADVANTAGES WITH DAICEL ANALYTICAL SERVICES

Integrated Services

Global Network

Quick TAT

Technical Expertise

Advanced Technologies

Seamless Communication