DAICEL

Sustainable Value Together

GMP ANALYTICAL SERVICES

PURIFICATION SERVICES

SYNTHESIS SERVICES

PHARMA SERVICES

USFDA COMPLIANT ANALYTICAL FACILITY

ISO ACCREDITATIONS: 9001:2015; 17025:2017

DEDICATED FACILITY FOR HP/CYTOTOXIC COMPOUNDS ANALYSIS

YOUR GLOBAL PARTNER FOR PHARMA SERVICES

As a wholly-owned subsidiary of Daicel Corporation, Japan, we redefine pharmaceutical excellence through our comprehensive offerings to meet the growing and varying needs of Pharma and Biopharma industry. Daicel Pharma Services include GMP Analytical Services, Purification Services, and Synthesis Services. Committed to enabling timely and safe drug development with improved cost efficiency, we support both domestic and global customers from initial development to commercialized products.

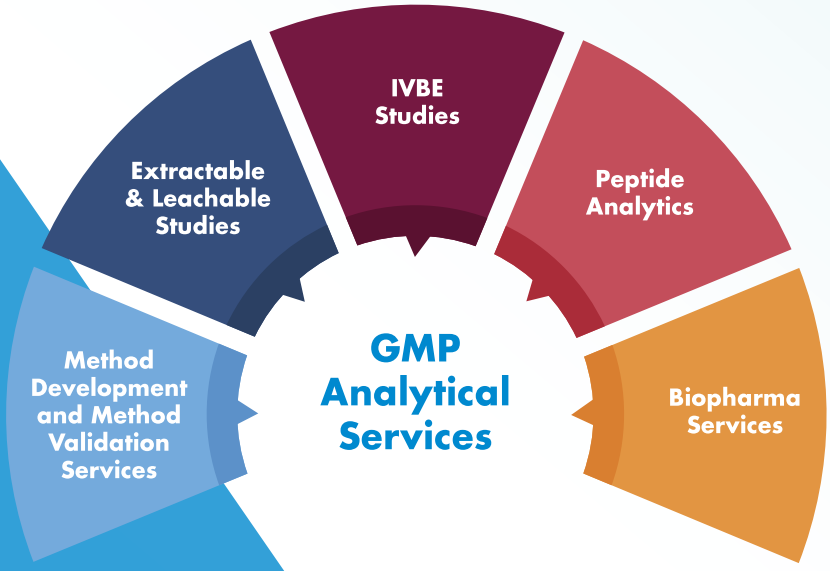
Daicel Analytical Services is equipped with state-of-the-art instrumentation and has qualified & experienced scientists with vast industry knowledge to develop and validate methods as per regulatory expectations.

Daicel offers a flexible approach which enables customers to choose from a wide spectrum of services to develop a project plan which meets their specific needs. 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.

TYPES OF ANALYTICAL SERVICES

- Dissolution Studies
- Non-Carryover Studies
- Genotoxic Impurities Quantification
- Ion Chormatography Studies (Multi detection systems)
- Forced Degradation Studies
- Assay methods by HPLC/UPLC
- Residual Solvents Methods by GC-MS
- Enantiomeric Purity Methods by Chiral HPLC
- Related Substances Methods by HPLC/UPLC (Multi detection systems)
- Stability Studies for APIs and Drug Products
- Extratable & Leachable Studies
- Microbiology
- Biopharmaceutical Services
- Peptide Services
- IVBE Studies
- Release Testing



Dedicated Lab for the Analysis of Cytotoxic and High Potent Drugs

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 analysis

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
  - Cream
  - 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




Packaging Materials

- Polycarbonate
- Rubber stoppers (Chlorobutyl, Brombutyl)
- Cyclic Olefin copolymer
- Polyvinyl chloride
- Low density polyethylene (LDPE)
- High density polyethylene (HDPE)
- Glass vials
- Closures
- Plungers

We also offer Glass Delamination Studies

Drug Products

- Inhalants / Metered Dose
- 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.

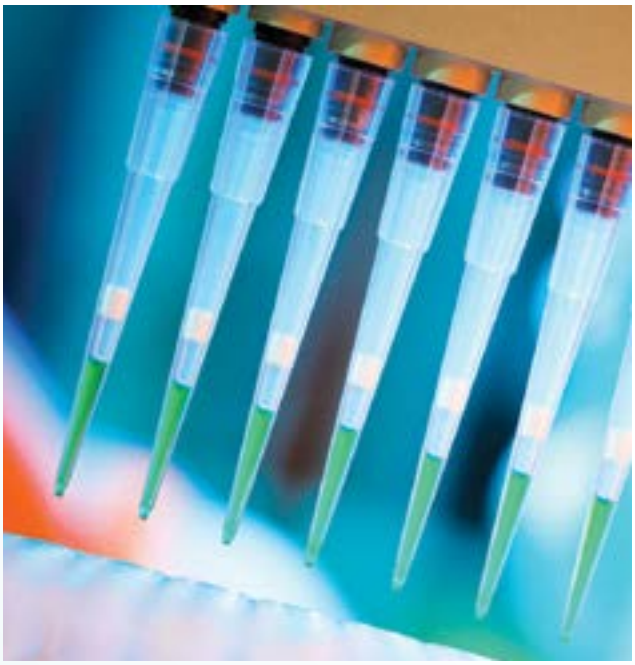



SPECIALITY STUDIES: IRON CARBOHYDRATE COMPLEX DRUGS

- 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

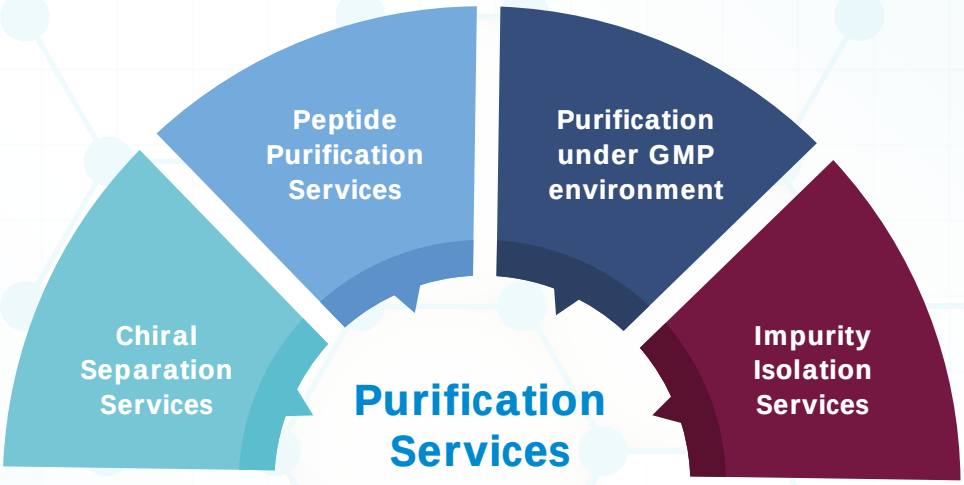
- Equivalence studies from Simple to Complex drugs
- Support Bioequivalence filing by conducting Dissolution studies, Equilibrium & Kinetic binding studies and Bioassays (including enzymatic assays) for different drugs like,
  - Sucralfate (Oral suspension & Tablets), Ferric citrate, Cholestyramine, Sevelamer Carbonate, etc.
- Equipped with Dissolution apparatus, IC, ICP-MS, Q-TOF, LC MS/MS, UPLC, SEC-HPLC, Multimode plate reader and other critical instruments



Analytics for Peptides and Biologics

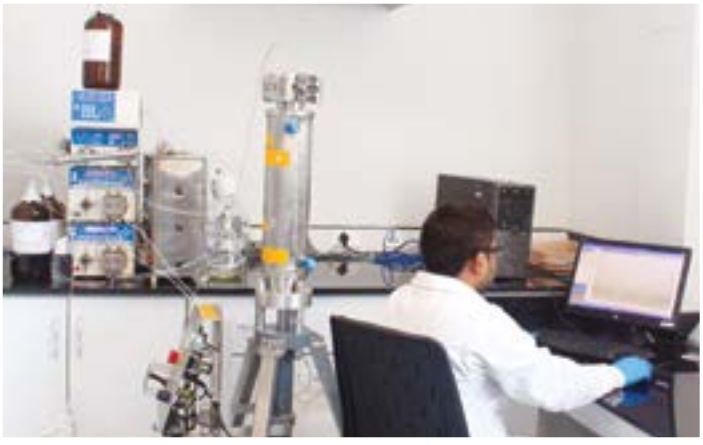
- Physico chemical characterization of Peptides and Biologics
- Higher Order Structural characterization of Peptides
- Lot release assays for Peptides and Biologics
- Impurity Profiling
- Bioassays for Peptides and Biologics
- Neutralizing antibody assays for Biologics
- Biosimilarity assessment studies
- Residuals Testing by ELISA
  - Protein A
  - Benzonase
  - Bovine Serum Albumin (BSA)
  - Host Cell Protein (HCP)
  - Human Serum Albumin (HSA)
  - Insulin
  - Long-IGF3
- Bioidentity methods as per USP monograph and general chapters
- Custom based Bioassays

Successful FDA audits in 2016, 2019 and 2023



Chiral Separation Services

- Equipped with Prep HPLCs/SFCs, Mass directed Prep HPLC
- Equipped with full range of preparative Chiral Columns
- Separating the quantities ranging from 50 mg to Multi kg of racemic mixtures
- Guaranteed chiral purity of 99% and yield of 90% Rich experience in handling critical separations



Peptide Purification Services

- Rich experience in handling peptide molecules purification ranging from 100mg to 100gm batches: NCEs/ APIs
- Specifications: >99.5% chemical purity; Impurity: NMT 0.1%

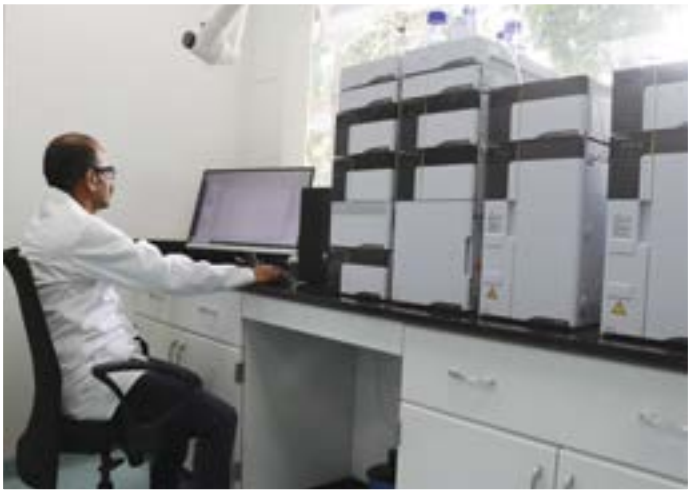
Purification under GMP environment

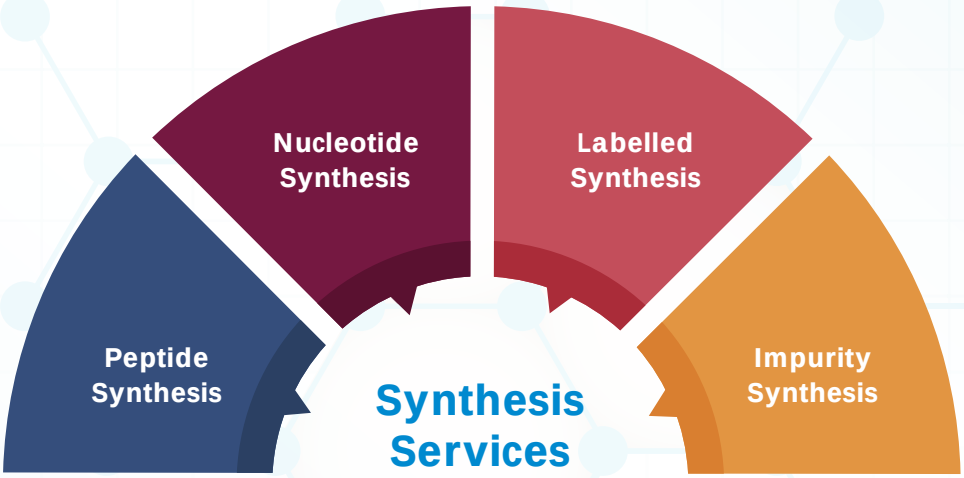
ISO 9001:2015 QMS accredited

- Prep LC separation / purification under GMP environment
- Column Size: (110x 500) mm; (80 x 500) mm
- Handling Capacity: 100 g – 50 Kg
- COA release from US-FDA compliance analytical lab

Impurity Isolation Services

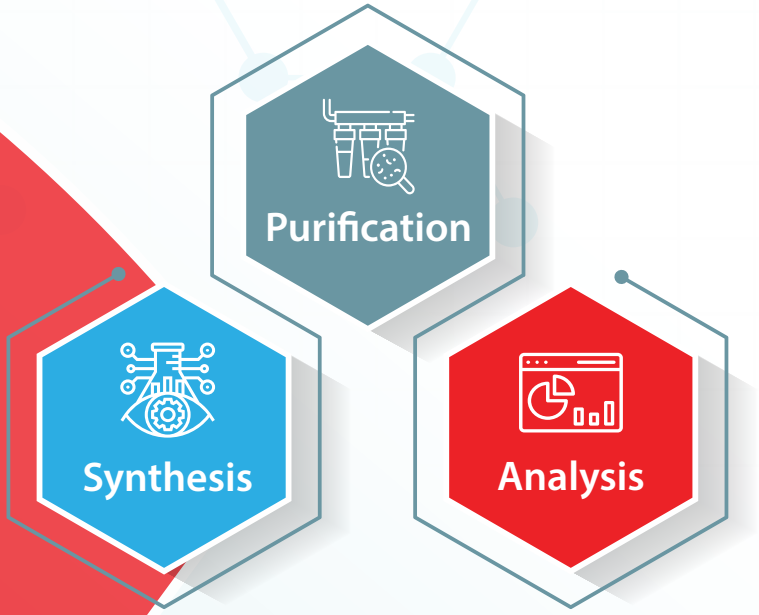
- Equipped with Prep HPLCs/SFCs, Flash LC with ELSD, Mass directed Prep HPLC
- Equipped with Analytical HPLCs/SFCs and full range of columns
- Achiral selectivity of immobilized chiral columns
- Rich experience in isolating impurities from APIs and Drug Products
- Resolved several challenges in impurity isolations
- Expertise in isolating unstable impurities
- Trace level impurities isolations (>0.05%)
- Structural Characterization





Peptide Synthesis

- Custom synthesis of peptides for pre-clinical and clinical
  - 10-100g scale, purity range >95-98%
- Peptide Libraries for biological screening
- Custom peptide impurities
  - Process related impurities
  - Degradation impurities
  - Excipients interaction
- Custom Isotope labeled peptides and metabolites
  - Deuterium & 13C Labeled



Process Development and Tech Transfer

- Process development of Therapeutic Peptides
- Complete technology development - Synthesis | Purification Technology | Analytical Method development and Validations
- Tech transfer to Manufacturing site
- Post Tech transfer support

Nucleotide Synthesis

- Custom synthesis of new generation nucleotides-Mono, Di, Cap M-RNA
- Contract research on Nucleotides and their analogues with novel approach
- Synthesis from mg to multi gram scale
- Supported by advanced Analytical and Purification facilities

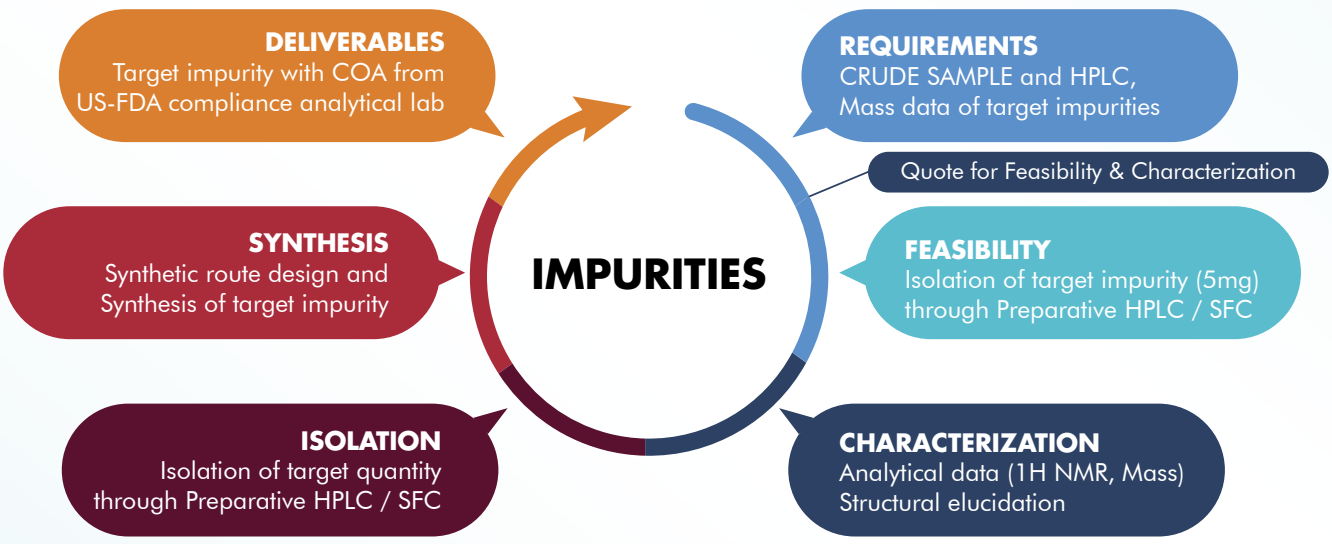
Labelled Synthesis

- Stable isotope labelled synthesis of NCEs in multi-gram scale.
- Labelled synthesis of shelf-stable, 2H and 13C labelled APIs, metabolites and Glucuronides for bio-analytical studies
- Expertise in Deuterium Labelling of Peptide APIs and Impurities
- Thorough testing to ensure no interference from the corresponding unlabelled compounds.

Impurity Synthesis

- Custom Impurity Synthesis of target known impurities from mg to multi gram scale Isolation, characterisation and Synthesis of unknown impurities from APIs / Drug products.
- Expertise in all kind of isomeric impurities, degradation impurities, metabolites and Glucuronides
- Our process starts with direct communication with our customers, discussing data and determining feasibility. After full characterization, the target impurity is then isolated through preparative HPLC/ SFC chromatography or directly synthesized. The desired amount is delivered with characterisation report and CoA from our US-FDA compliant analytical lab.

OUR STRATEGY (ISOLATION / CHARACTERIZATION / SYNTHESIS)



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DAICEL CHIRAL TECHNOLOGIES
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