



Daicel Pharma Services offers innovative analytical solutions to support timely and safe drug development with improved cost efficiency. Our GMP facilities are FDA compliant and offer a full suite of solutions including stability studies, microbiology, peptide and biologics. Whether your project requires full or supplemental support, we have the experience and flexible service options to meet your needs, on time and within budget. www.daicelpharmaservices.com

Method Development / Validation / Transfer Studies

- Stability
- Extractable & Leachable
- In-Vitro
- Glass Delamination

Microbiology

Microbiological test method development, method validation and method verifications services are offered for below mentioned tests among other extensive testing:

- Microbial limit test MLT
- Sterility test – Closed method / Open method
- Bacterial endotoxin test (BET)
- Antibiotic assay – Cylinder method
- Preservative efficacy test
- Disinfectant Validations
- Non routine validations/studies (Endotoxin recovery studies and
- Microbial recovery studies

Peptide Analytical Offerings

- Aggregation (SEC-HPLC)
- Related impurities and assay by HPLC
- Aggregation by SEC-MALS, DLS and Fluorescence
- Amino acid sequencing
- Intact peptide molecular weight
- Related impurities by HR-MS including method validation
- Oxidation, deamidation and disulfide analysis
- Peptide mapping
- Glycation, Methylation and isomerization
- Higher order structure analysis

Custom Impurity Synthesis and Labeled Synthesis

Daicel Pharma Standards offers custom synthesis of target impurities of known structures. The Daicel Pharma Standards highly experienced and qualified scientific team is capable of synthesizing even the most complex impurities (not limited to small molecules) as well as peptides. Our project management system ensures seamless communication with customers and on time deliveries with assured quality.

Daicel Pharma Standards offers custom labeled synthesis of NCEs for customer pharmacokinetic studies. Daicel has the capacity to manufacture these high-purity/quality labeled NCEs in multi-gram scale.

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