DAICEL CHIRAL TECHNOLOGIES
(INDIA) PRIVATE LIMITED

DAICEL
The Best Solution for You

GMP ANALYTICAL SERVICES

ACCREDITATIONS

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health
US-FDA Compliance Facility

DNV·GL
ISO 9001:2015 certified

OFFERINGS

METHOD DEVELOPMENT → METHOD VERIFICATION → METHOD VALIDATION → METHOD TRANSFER

Core Area: Analytical Method Development (AMD) and Analytical Method Validation (AMV) studies for IND, DMF and ANDA filings

Type of AMD & AMV studies:

a. Related Substances Method by HPLC / UPLC
b. Assay Method by HPLC / UPLC
c. Forced Degradation Studies
d. Enantiomeric purity method by chiral HPLC
e. Residual Solvents method by GC-HS
f. Dissolution Studies
g. Non-carryover Studies
h. Genotoxic impurity quantification
i. Ion Chromatography Studies (Counter ions)
j. Elemental impurities by ICP-MS

PRODUCT CATEGORY

- Key Starting Materials
- Intermediates
- Drug Substances
- Drug products: Solid Orals | Transdermal | Parenterals | Ophthalmic | Topical

US-FDA COMPLIANCE ANALYTICAL SERVICES FACILITY

CHROMATOGRAPHY

- ✓ HPLC / UPLC with Multi detection systems
  UV, PDA, RI, FLD and CAD
- ✓ IC with Conductivity detector
- ✓ GC - HS with FID

HYPHENATED TECHNIQUES

- ✓ UFLC-MS/MS
- ✓ GC-HS/MS/MS
- ✓ ICP-MS

NETWORK

21 CFR Part 11 Compliance Software

- ✓ Empower-3
- ✓ Lab Solutions

Website: www.chiraltech.com
e-mail : chiral@chiral.daicel.com

Lab No.4A, Phase III, IKP Knowledge Park,Genome Valley, Turkapally Village,
Shamirpet, R.R. Distt., Hyderabad - 500078, Telangana, India.

Tel No. +91-40-23383 700,701,702.
Fax No. +91-40-23480104.