

Daicel Pharma Standards

Impurity
Standards

Stable
Isotope Labelled
Standards

Peptide
Standards



PHARMA STANDARDS

Impurity Standards

- » Specialists in isomeric impurities, degradation impurities, metabolites and Glucuronides
- » Ready to ship inventory of complex impurity standards
- » Custom Impurity Synthesis from mg to multi gram scale delivered with characterization report and COA.
- » Isolation of Impurities from APIs / Drug Products
- » Characterisation and Synthesis of isolated impurities

Labelled Standards:

- » Stable Isotope Labelled Standards of APIs, Metabolites and Glucuronides for bioanalytical studies
- » Extensive COA including quantification of unlabelled compound
- » Expertise in Deuterium Labelling of Peptide APIs and Impurities
- » Deuterium Labelled Synthesis of NCEs

Peptide Impurity Standards:

- » Custom Peptide Impurity Synthesis using natural and unnatural amino acids
- » Expertise in both cyclic and linear peptides
- » Peptide dimers, di & tri sulfide bridges
- » Large inventory of generic peptide drug impurities
- » Extensive characterisation data with COA

State-of-the-art Facility

» Synthesis R&D Facility



» Purification Facility



» US-FDA Compliant Analytical Facility



CoA from US-FDA Compliant Analytical Facility

Anti-Arthritic and Anti Inflammatory Drugs

Apremilast
Aspirine
Baricitinib
Chloroquine
Ethacizine
Fingolimod
Flurbiprofen
Hydroxychloroquine
Ibuprofen
Indometacin
Leflunomide
Mesalamine
Methotrexate
Pelubiprofen
Pentoxifylline
Raloxifene
Siponimod
Teriflunomide
Tofacitinib

Anti-Cancer Drugs

Afatinib
Acalabrutinib
Anastrozole
Apalutamide
Azacitidine
Baricitinib
Bendamustine
Binimetinib
Bosutinib
Branebrutinib
Cabozantinib
Cyclophosphamide
Darolutamide
Dasatinib
Deucravacitinib
Duvelisib
Elagolix

Enzalutamide
Erlotinib
Fedratinib
Fulvestrant
Gefitinib
Gemcitabine
Glasdegib
Ibrutinib
Ivosidenib
Lenalidomide
Lenvatinib
Melphalan
Melphalan
Methotrexate
Nelarabine
Neratinib
Nilotinib
Nintedanib
Olaparib
Osimertinib
Palbociclib
Pazopanib
Pemetrexed
Pemigatinib
Pomalidomide
Relugolix
Resiquimod
Ribociclib
Ruxolitinib
Selpercatinib
Sorafenib
Sotorasib
Sumatriptan
Sunitinib
Suplatast tosilate
Tamatinib
Tamoxifen
Temozolomide
Tepotinib
Tivozanib
Trametinib
Tucatinib
Zanubrutinib

Anticoagulant Drugs

Apixaban
Dabigatran
Edoxaban
Rivaroxaban
Warfarin

Anti-Diabetic Drugs

Saxagliptin
Dapagliflozin
Empagliflozin
Linagliptin
Lobeglitazone
Nateglinide
Sitagliptin
Teneligliptin
Vildagliptin

Anti-Hypertensive & Cardiovascular Drugs

Ambrisentan
Amlodipine
Azelnidipine
Azilsartan
Bisoprolol
Carvedilol
Clinidipine
Cxybutynine
Diltiazem
Dobutamine
Enalapril
Felodipine
Ivabradine
Labetalol
Labetalol
Lapatinib

Lasmiditan
Lercanidipine
Levosimendan
Lisinopril
Losartan
Manidipine
Metoprolol
Nebivolol
Nicaridipine
Olmesartan
Perindopril
Propranolol
Ramipril
Regadenoson
Riociguat
Sacubitril
Ticagrelor
Trimetazidine
Valsartan
Verapamil
Vericiguat

Anti-Microbial Drugs

Acyclovir
Adefovir
Alafosfaline
Albendazole
Amoxicillin
Amphotericin
Amprenavir
Atazanavir
Aztreonam
Bedaquiline
Benvitimod
Brequinar
Cabotegravir
Cefadroxil
Cefazolin
Cefdinir

Cefoxitin
Cefprozil
Ceftazidime
Cefuroxime axetil
Ciprofloxacin
Clindomycine
Daclatasvir
Darunavir
Demeclocycline
Dimethomorph
Dolutegravir
Doxycycline
Efinaconazole
Elvitegravir
Emtricitabine
Favipiravir
Fluconazole
Fosamprenavir
Foscarnet
Fosfomycin
Ganciclovir
Gemifloxacin
Isovuconazolium sulfate
Lamivudine
Letermovir
Lincomycine
Linezolid
Lopinavir
Lumafantrine
Marbofloxacin
Mebendazole
Minocycline
Molnupiravir
Mupirocin
Nirmatrelvir
Oseltamivir
Piperacillin
Posaconazole
Primaquine
Raltegravir
Ramdesivir
Ravuconazole

Remdesivir
Rilpivirine
Ritonavir
Sofosbuvir
Sparfloxacin
Tenofovir Alafenamide
Tenofovir Disproxil
Tigecycline
Valacyclovir
Valganciclovir
Voriconazole

Gastrointestinal Drugs

Clomefene
Elobixibat
Eltrombopag
Eluxadoline
Mebeverine
Odevixibat
Ondansetron
Palonosetron
Phenylephrine
Pinaverium
Pitofenone
Tolvaptan

Contrasting Agents

Iohexol
Iopamidol
Iodixanol
Isosulfan Blue

Contraceptive Agents

Ormeloxifene
Ulipristal acetate

Gastroprokinetic Agents

Candesartan
Dexlansoprazole
Mosapride
Omeprazole
Rabeprazole
Tegoprazan
Vonoprazan

Anti Gaucher's Drugs

Eliglustat
Febuxostat

Harmonal Drugs

Biopterin
Epinephrine
Estrone
Levothyroxine
Liothyronine
Melatonin
Progesterone
Sapropterin

Neurological Drugs

Aripiprazole
Brexipiprazole
Brivaracetam
Bupropion
Cardidopa
Cisatracurium Besilate

Cromolyn
Dexmedetomidine
Dezocine
Dihydro Ergotamine
Dimetindene
Droxidopa
Eletriptan
Flumazenil
Fluphenazine
Fluvoxamine
Ivacaftor
Levitriacetam
Lumateperone
Lurasidone
Medetomidine
Mepivacaine
Mirogabalin
Olanzapine
Orphenadrine
Paliperidone
Paroxetine
Pramipexole
Pregabalin
Proparacaine
Prucalopride
Pyridostigmine
Quetiapine
Ramelteon
Rasagiline
Rimegepant
Risperidone
Rivastigmine
Rotigotine
Scopolamine
Sertraline
Tapentadol
Tasimelteon
Tetrabenazine
Thiothixene
Tiagabine
Topiramate
Tranlycypromine

Trifluoperazine
Ubrogapant
Valbenazine
Valproate
Venlafaxine
Vilazodone
Viloxazine
Vortioxetine
Ziprasidone
Zolmitriptan

Ophthalmic Drugs

Alcaftadine
Bepotastine
Brinzolamide
Dorzolamide
Fluphenazine
Lifitegrast
Netarsudil
Olopatadine
Pilocarpine

Overactive bladder Inhibiting Drugs

Fesoterodine
Mirabegron
Oxybutynin
Silodosin
Vibegron

Pulmonary Drugs

Ambrisentan
Arformoterol
Bosentan
Fenoterol
Formoterol
Indacaterol
Macitentan

Salbutamol
Salmeterol
Selexipag
Sildenafil
Tiotropium bromide
Umeclidinium bromide
Vilanterol
Zileuton

Vitamins

Benfotiamine
Cholecalciferol
Doxercalciferol
Ergocalciferol
Isotretinoin
Phytonadione (Vit K)
Retinoic Acid

Steroid Drugs

Abiraterone
Clobetasol
Desogestrel
Difluprednate
Dydrogesterone
Eplerenone
Ethinylestradiol
Etonogestrel
Finasteride
Flumethasone
Fluocinolone
Halobetasol
Hydrocortisone
Levonorgestrel
Loteprednol
Medroxyprogesterone
Methylprednisolone
Mometasone Furoate
Norethindrone Acetate
Progesterone
Testosterone

Peptide Impurities

Calcitonin

Asp-26-Calcitonin
Glu-14-Calcitonin
Glu-20-Calcitonin
Asp (3)-Calcitonin
Des (32,31) Thr, Pro-Calcitonin
Calcitonin Parallel Dimer
Calcitoninyl glycine
Ser(Ac)5-Calcitonin
Des-(32,31) Thr-Pro Calcitonin Acid
Truncated (32-27)- Calcitonin
Trisulfide-Calcitonin
1-2 Hydrolysis Calcitonin
Calcitonin Salmon D10 Impurity
1,7 bis(3-sulfo-L-Ala)-
Calcitonin salmon
1,7 bis(3-sulfo-L-Ala)-
Calcitoninyl glycine
Truncated (32-20)-Calcitonin
Truncated (32-29)-Calcitonin
Truncated (32-28)-Calcitonin
Fragment (27-32)-Calcitonin salmon
Fragment (28-32)-Calcitonin salmon
Cyclo-Asn(3)-Calcitonin
Cyclo-Asn(26)-Calcitonin
Ala(CN)3-Calcitonin
Des-Thr(6)-Calcitonin
Des-Thr(21)-Calcitonin
Asp(3)-Truncated[32-29]-Calcitonin
Asp(26)-Truncated[32-29]-Calcitonin
Glu(14)-Truncated[32-29]-Calcitonin
Glu(20)-Truncated[32-29]-Calcitonin

Cetrorelix

Cetrorelix D10
Des-Amido-Cetrorelix
L-Ala(10)-Cetrorelix
Des-Acetyl-Cetrorelix
Des-D-Ala-Cetrorelix
Endo-3-D-Pal-Cetrorelix

Daptomycin

Daptomycin β -Isomer
Anhydro-Daptomycin
Daptomycin (RS-1)
Daptomycin Lactone Hydrolysis
Daptomycin impurity-1
Daptomycin Impurity-B1/II
Daptomycin Impurity-B2
Daptomycin impurity-5
Daptomycin Impurity-6
Daptomycin Impurity-7
Daptomycin Impurity-8
Daptomycin Impurity-3
Daptomycin Impurity-4
Isodecyl acyl isomer
Impurity RS-7b
Impurity RS-2

Ganirelix

L-Ala(10)-Ganirelix
D-Ser(4)-Ganirelix

Icatibant

Des-D-Arg(1)-Icatibant
Des-L-Arg(2)-Icatibant
L-Arg(1)-Icatibant
(1-6)-Icatibant
(7-10)-Icatibant
Ac-Icatibant

Lanreotide

Lanreotide D8 TFA salt
Des-Thr(8)-Lanreotide
N-Ac-Lanreotide
L-Nal-Lanreotide
Lanreotide Acid

Leuprolide

Leuprolide- Impurity-12
D-Trp-Leuprolide
Leuprolide- Impurity-6
Leuprolide- Impurity-8
D-Ser-Leuprolide
D-His-Leuprolide
Leuprolide-Metabolite(pentapeptide)
(O-Acetyl-L-Ser)-Leuprolide
L-Leu (6)-Leuprolide
D-Leu-Leuprolide
Ac(2-9) Leuprolide
D-Tyr-Leuprolide
Leuprolide D10 (labelled)
Leuprolide impurity(1-5)
Leuprolide impurity(1-8)
Des-Ser(4)-Leuprolid
[1-(5-Oxo-D-proline)]Leuprorelin
[2-D-histidine,4-D-serine]leuprorelin
D-Arg(8)-Leuprolide
D-Pro(9)-Leuprolide

Linaclotide

Asp(7)-Linaclotide
Ac-Linaclotide
Des-Tyr(14)-Linaclotide
Cys(1)-IMD-Linaclotide

Liraglutide

D-His(1)-Liraglutide
D-Glu(3)-Liraglutide
D-Ser(8)-Liraglutide
Des-Gly(4)-Liraglutide
Des-Ser(8)-Liraglutide
Des-Gly(29)-Liraglutide
Des-Gly(31)-Liraglutide
D-Arg(28)-Liraglutide
Trp(O)-Liraglutide
Glu(17)-Liraglutide
[3-31]-Liraglutide
[4-31]-Liraglutide
[5-31]-Liraglutide
[6-31]-Liraglutide
[7-31]-Liraglutide
[9-31]-Liraglutide
[10-31]-Liraglutide
Des-Ala(2)-Liraglutide
Des-Thr(5)-Liraglutide
D-allo-Thr(11)-Liraglutide
D-allo-Thr(13)-Liraglutide
D-Val(16)-Liraglutide
D-Ser(17)-Liraglutide
D-Ser(18)-Liraglutide
Imp-J (Formaldehyde-Adduct)
Trp(Ac)-Liraglutide
Iso-Asp-Liraglutide
D-Glu(side chain)-Liraglutide
[1-28]-Liraglutide
Iso-Asp(9)-Liraglutide

Oxytocin

Ac-Oxytocin
Asp 5- Oxytocin
Glu 4-Oxytocin
Leu 3-Oxytocin
Oxytocic Acid
D-Asn 5-Oxytocin
Ala (3-CN) 5-Oxytocin
Parallel Dimer- Oxytocin
Antiparallel Dimer Oxytocin

Octreotide

D-Thr(6)-Octreotide
D-Cys(2)-Octreotide
Ac-Octreotide
Trp(4)-Octreotide
Lys(Ac)-Octreotide
Des-Threoninol-Octreotide
D-Cys(7)-Octreotide
Threoninol(Ac)
8-Octreotide
Linear octreotide
L-Phe(1)-Octreotide
Des-D-Phe(1)-Octreotide
Des-D-Trp(4)-Octreotide
Des-Lys(5)-Octreotide
Octreotide Acid
D-Phe(3)-Octreotide
D-allo-Thr(6)-Octreotide
(N-O) acyl isomer of Octreotide
Trisulfide Octreotide
Octreotide D8(labelled)
OCA Thr-O-Glycolic ester
Lys-Glycolyl-Octreotide

Semaglutide

Semaglutide WRS
Semaglutide D5
Des-Glu(3)-Semaglutide
Endo-Gly(4)-Semaglutide
D-His(7)-Semaglutide
Des-His(7)-Semaglutide
Des-Gly(10)-Semaglutide
Des-Thr(11)-Semaglutide
Endo-Gly(10)-Semaglutide
iso-Asp-Semaglutide
Trp(4-hydroxybenzyl)25-Semaglutide
Semaglutide+14 impurity

Somatostatin

D-Ala(1)-Somatostatin
D-Asn(5)-Somatostatin
D-Cys(3)-Somatostatin
D-Lys(4)-Somatostatin
D-Phe(6)-Somatostatin
D-Cys(14)-Somatostatin
D-Lys(9)-Somatostatin
D-Phe(7)-Somatostatin
D-Phe(11)-Somatostatin
D-Ser(13)-Somatostatin
D-allo-Thr(10)-Somatostatin
D-allo-Thr(12)-Somatostatin
D-Trp(8)-Somatostatin
[3-14]-Somatostatin
Ac-[3-14]-Somatostatin
Des-Ala(1)-Somatostatin
Ac-Des-Ala(1)-Somatostatin
Asp(5)-Somatostatin
Des-Asn(5)-Somatostatin
Des-Gly(2)-Somatostatin
Des-Ser(13)-Somatostatin
Des-Thr(12)-Somatostatin
Di-Ala(1)-Somatostatin

Di-Gly(2)-Somatostatin
Di-Thr(12)-Somatostatin
Di-Trp(8)-Somatostatin
Endo [Ser-Cys(Acm)]-Somatostatin
DICU (7-14)-Somatostatin

Under development

Somatostatin Dimer
Somatostatin Trimer

Teriparatide

Met(O)-8,18-Teriparatide
Teriparatide Dimer
PTH(31-34)-Acid Impurity
PTH(31-34)-Teriparatide
Met(O)-8 Teriparatide
Met(O)-18 Teriparatide

Vasopressin

Gly 9-Vasopressin
Glu (4)-Vasopressin
Asp(5)-Vasopressin
Di-sulfonic acid- AVP
Des-Gly-Vasopressin
Endo-Gly-Vasopressin
Ac-Vasopressin
Vasopressin D5 (labelled)
Trisulfide AVP
D-Asn-Vasopressin
Des-Pro-Vasopressin
Gln(Acm)-Vasopressin
His(2)-Vasopressin
D-Tyr-Vasopressin
D-Arg(8)-Vasopressin
D-Cys(1)-Vasopressin
D-Cys(6)-Vasopressin
D-Pro(7)-Vasopressin
Des-Gly-OH-Vasopressin
D-Phe(3)-Vasopressin
Parallel Dimer
Antiparallel Dimer
 β -Asp(5)-Vasopressin
Ac-Asp(5)-Vasopressin
Leu(7)-Vasopressin
Glu(4)-Gly-OH-Vasopressin
Lysine-Vasopressin

Miscellaneous

Des-Asn(1)-Plecanatide
N,N'-dimethyl-Gly-
Desmopressin
UD: Gln(Acm)-Desmopressin
Asn(Acm)-Desmopressin
Met(O)-Tetracosactide
Triptorelin Dimer
Triptorelin Trimer

Popular Chiral Isomers and Impurities

Alafosfalin

Alafosfalin Chiral Isomers

S,S-Isomer
R,R-Isomer
S,R-Isomer

Brivaracetam

S, S-Isomer (Diastereomer-1)
R, R-Isomer (Diastereomer-2)
R, S-Isomer (Enantiomer)
Brivaracetam Racemic Mixture
Brivaracetam Acid Racemic Mixture
Brivaracetam Acid Impurity (S, R Isomer)
Acid impurity (R, S Isomer)
Acid impurity (S, S Isomer)
Acid impurity (R, R Isomer)

Cabotegravir

Cabotegravir Chiral Isomer

R,S-Isomer
S,S-Isomer
R,R-Isomer

Darunavir

Darunavir Chiral Isomers

3R,3aR,6aS-Isomer
3S,3aR,6aS-Isomer
3S,3aS,6aR-Isomer

Darunavir BIS THF Chiral Isomers

R = NHS (N-Hydroxy Succinamide)
R = 4-Nitro Phenyl Carbonate
BIS THF HNS 3R,3aR,6aS
BIS THF HNS 3S,3aR,6aS
BIS THF HNS 3S,3aS,6aR
BIS THF 4-NO₂-Ph-Carb.3R,3aR,6aS

BIS THF 4-NO₂-Ph-Carb.3S,3aR,6aS
BIS THF 4-NO₂-Ph-Carb 3S,3aS,6aR.

Darunavir Furanone Chiral Isomers

Furanone RSS Isomer
Furanone RRS Isomer
Furanone SRR Isomer
Furanone SSR Isomer

Emtricitabine

Emtricitabine Chiral Isomers

S,S-Isomer
R,R-Isomer
S,R-Isomer

Dihydratetrabenazine

Dihydro Tetrabenazine Chiral Isomers & Impurities

(2S,3R,11bR)-DHTBZ
(2R,3R,11bR)-DHTBZ
(2R,3S,11bS)-DHTBZ
(2S,3S,11bS)-DHTBZ
 β -DHTBZ-D6
 α -DHTBZ-D6
9-Desmethyl α -DHTBZ
9-Desmethyl α -DHTBZ D6
3-Butyl TBZ

Dolutegravir

Dolutegravir Chiral Isomers and Impurities

S,R-Isomer
S,S-Isomer
R,R-Isomer
2-Desfluoro Impurity
4-Desfluoro Impurity
Didesfluoro Impurity
2.6-Difluoro Impurity
O-Methoxy Impurity

O-Ethoxy Impurity
Openchain Impurity
Openchain Methoxy
Deshydroxy Impurity

Dorzolamide

Dorzolamide Enantiomer (EP Imp. A)
Dorzolamide Diastereomers (EP Imp. B)
Dorzolamide intermediate Diastereomers
Dorzolamide Intermediate Enantiomer
Dorzolamide N-Desethyl N-Acetyl Analog
Dorzolamide Maleic acid adduct

Efinaconazole Epoxy Intermediate

API isomer (2R,3S)-EFC-III
Enantiomer (2S,3R) -EFC-III
Diastereomer (2S,3S)-EFC-III
Diastereomer (2R,3R)-EFC-III

Efinaconazole

Efinaconazole Enantiomer (2S,3S)
Efinaconazole Diastereomer (2S,3R)
Efinaconazole Diastereomer (2R,3S)

Efinaconazole Diol Intermediate

API isomer (2R,3R)-EFC-II
Enantiomer (2S,3S)-EFC-II
Diastereomer(2S,3R)-EFC-II
Diastereomer(2R,3S)-EFC-II

Eliglustat

Eliglustat Chiral Isomers and Impurities

S,R-Isomer
R,S-Isomer
S,S-Isomer &

Hemitartarte salts
Oxopropen Imp.
O-Octyl Impuity
N-Oxide Impurity
N-Acetyl Impurity
Heptyl analogue Imp
Nonoyl Analogue Imp
Decyl Analogue Imp

Edoxaban

Edoxaban Chiral Isomers and Impurities

Chiral Isomers
R,S,R-Isomer
R,S,S-Isomer
R,R,S-Isomer
R,R,R-Isomer
S,S,S-Isomer
S,R,R-Isomer
S,S,R-Isomer

Process Related & Degradation Impurities

N-Oxide Impurity
N-Des Methyl Impurity
Carboxylic Acid Impurity
N-Des Methyl Edoxaban-coupled
N-Des Methyl Edoxaban-coupled
Impurity
Pyridine N-Oxide Impurity

Edoxaban KSM Chiral Isomers

R,S,R-Isomer
R,S,S-Isomer
R,R,S-Isomer
R,R,R-Isomer
S,R,S-Isomer
S,S,S-Isomer
S,R,R-Isomer
S,S,R-Isomer

Formoterol & Arformoterol

Formoterol & Arformoterol Chiral Isomers

R, R - Isomer

R, S - Isomer

S, R - Isomer

S, S - Isomer

Mixture of All Isomers

Formoterol & Arformoterol Impurities Process Impurities

Formoterol EP impurity A

Formoterol EP impurity B

Formoterol EP impurity C

Formoterol EP impurity D

Formoterol EP Impurity E

Formoterol EP Impurity-G

N-Benzyl Formoterol (Imp H)

Formoterol EP Impurity-I

O-Benzyl N-Benzyl Formoterol (Imp-N)

Formoterol N-Methyl Impurity (Imp-1)

N-(2-(benzyloxy)-5-(1-hydroxyethyl)
phenyl)formamide

N-(2-(benzyloxy)-5-ethylphenyl)formamide

Formoterol impurity-2

Formoterol impurity 3

Formoterol desphenolic hydroxy impurity

Arformoterol Diformylated Amino Impurity

Arformoterol O-Formyl

N-Acetyl Amino Impurity

Arformoterol Amino Dimer impurity

Indacaterol

Indacaterol Chiral Isomers and Impurities

Indacaterol Enantiomer

O-Benzyl Impurity

Reduced Imp of Indenamine

Di-Desethyl Indenamine

Mono-Ethyl Indenamine

Isavuconazole

Isavuconazolium Sulphate

Isomers SS, SR & RS

Isavuconazole Isomers SS, SR & RS

Hydroxy Nitrile Int. Isomers SS, RR,
SR & RS

Thiamide Int. Isomers SS, RR, SR & RS

Lamivudine

Lamivudine Chiral Isomers

S,S-Isomer

R,R-Isomer

S,R-Isomer

Molnupiravir

Molnupiravir Chiral Isomers & Process Related Impurities Chiral Isomers

Enantiomer

α -Isomer

Process Impurities

Des Isobutyl Impurity

Uridine Analogue

Cytidine Analogue

Acetonoid Impurity

Acetonoid Cytidine Impurity

Acetonoid Des Isobutyl Impurity

Nebivolol

Nebivolol Chiral Isomers

R,S,S,R-Isomer

R,R,S,S-Isomer

S,R,R,S-Isomer

S,S,S,S-Isomer

S,R,S,R-Isomer

S,R,R,R-Isomer

R,S,S,S-Isomer

R,S,R,R-Isomer

R,R,R,R-Isomer

S,R,S,S-Isomer

Oxybutynine

Oxybutynine R- Isomer
Oxybutynine S- Isomer
Oxybutynine R- Isomer D10
Oxybutynine S- Isomer D10
Oxybutynine D10
Desethyl Impurity & D5
Related Compound A, B & C
Diphenyl Analogue
Ethyl Propyl Analogue
Desethoxy Oxybutynine Impurity
N-Substituted Allyl Impurity

Oseltamivir

Oseltamivir Chiral Isomers & Impurities

Chiral Isomers

R,R,R-Isomer
R,S,R-Isomer
R,S,S-Isomer
S,S,R-Isomer
S,S,S-Isomer
S,R,S-Isomer
S,R,R-Isomer

Process Related & Degradation Impurities

Monograph Impurities
Allyl impurities
Dihydro Impurity
Diamine Impurity
Pyrrol Impurities
Furan Impurities
Citrate adducts
Glucose adduct

Perindopril

S,S,S,R,S Isomer
S,S,S,R,R Isomer
S,R,S,S,S Isomer
EP Impurity B
EP Impurity C
EP Impurity D
EP impurity F
EP Impurity H
EP Impurity J

Phytonadione

Phytonadione Chiral Isomers & Impurities

Chiral Isomers

S,S,E-Isomer
S,R,E-Isomer
R,S,E-Isomer
R,R,Z-Isomer
S,S,Z-Isomer
R,S,Z-Isomer
S,R,Z-Isomer
Doble Bond Isomer
1, 2 & 3

Peroxy Diastereomers
Epoxy Diastereomers

Dihydroxy

Diastereomers

Dihydroxy Epoxy -
Diastereomers

Process Related & Degradation Imp.

Hydroxy impurity
Peroxy impurity
2,3-Epoxy impurity
Trans Epoxy Impurity
Dihydroxy Impurity
Dihydro Impurity
Diacetoxy Impurity

Acetoxy Impurity
Menadion Impurity
Menadion Epoxy Impurity
Cyclized Menadion Impurity
Cyclized related Impurit
(Chromenol Impurity)

Remdesivir

Remdesivir Chiral Isomers & Impurities

Chiral Isomers

S,R,R-Isomer
S,S,S-Isomer
S,R,S-Isomer
R,R,R-Isomer
R,S,R-Isomer
R,R,S-Isomer
R,S,S-Isomer
n-Butyl S,S, Isomer
n-Butyl S,R,R Isomer
n-Butyl S,S,S Isomer
tert-Butyl S,S,R Isomer
Methyl S,S,R Isomer

Degradation Impurities

O-Des phosphate
Acetonide Impurity
Acetonide Impurity
Des Phenyl
Acid Impurity
Phenol Impurity
Phosphate Impurity
Des Phenyl

Alanine Impurity
Amide analogue

4-Nitro & pentafluoro Phenyl Alanine

Remdesivir Side chine Isomers

R = Pentafluoro Phenyl
R = 4-Nitro Phenyl
Pentafluoro Phenyl S,S-Isomer
Pentafluoro Phenyl S,R-Isomer

Perindopril

Pentafluoro Phenyl R,S-Isomer
Pentafluoro Phenyl R,R-Isomer
4-Nitro Phenyl S,S-Isomer
4-Nitro Phenyl S,R-Isomer
4-Nitro Phenyl R,S-Isomer
4-Nitro Phenyl R,R-Isomer

Trihydroxy Cyano Triazine

Remdesivir Side chain Impurities

α -Trihydroxy Cyano
Triazine
 β -Trihydroxy Cyano
Triazine
Tri-O-Benzyl Impurity
Mono-O-Benzyl
Impurity
Di N-Benzyl Impurity
Mono N-Benzyl Impurity

Regadenoson

Regadenoson α -Anomer & Impurities

Regadenoson
 α -Anomer
N,N-Dimethyl Impurity
Carboxylic
Acid Impurity
Methyl Ester Impurity

Ritonavir

Ritonavir Chiral Isomers & Impurities

Enantiomer
3R Isomer
Hydroxy Ritonavir
Hydroperoxy Ritonavir
Hydroxy Ritonavir Int.
Hydroperoxy Ritonavir Int.

Ethyl Analog
Diacyl Urea
Amino Alcohol Urea
Oxazolidinone Derivative
N-Deacylvaline Ritonavir
Hydantoin Aminoalcohol
Hydantoin-oxazolidinone
O-Acyl Isomer
Acetamidoalcohol
Boc Aminoalcohol
Isobutoxycarbonyl
Aminoalcohol
N,N-Dimethyl Carbomate Imp.
N-Methyl Carbomate Imp.
2,5-Thiazolylmethyl
Dicarbamate
Ureidovaline Isobutyl Ester
Ureidovaline Ritonavir

Sacubitril

Chiral Isomers

S,S-Isomer
R,R-Isomer
S,R-Isomer

Saxagliptin

Chiral Isomers

S,S-Isomer
R,R-Isomer
S,R-Isomer

Tranlycypromine

Chiral Isomers & Impurities

R-Tranlycypromine
S-Tranlycypromine
R-Tranlycypromine-D5
S-Tranlycypromine-D5
Trans Hydrazide
Cis Hydrazide

Tenofovir Alafenamide

Tenofovir Alafenamide Chiral Isomers & Impurities Chiral Isomers

R,R,R-Isomer
R,R,S-Isomer
R,S,R-Isomer
S,S,S-Isomer
S,R,S-Isomer
S,R,R-Isomer
S,S,R-Isomer
Methyl Ester S,R,S
Methyl Ester R,R,S

Process Related & Degradation Impurities

TAF-PMPA Isopropyl Alaninate
TAF Regio isomer
PMPA Anhydride
TAF Di-Phenyl impurity
TAF Di-Isopropyl Alaninate
TAF Di-Isopropyl Impurity
TAF-Impurity-E
TAF-Impurity K

Teneligliptin

Teneligliptin Chiral Isomers
S,S-Isomer
R,R-Isomer
S,R-Isomer

Voriconazole

Voriconazole Enantiomer (EP Imp D)
Voriconazole Diastereomers
Voriconazole Dimer impurity (Imp-15)
Voriconazole EP Imp. A
Voriconazole EP Imp. C

Some Popular API Chiral isomers

Ivosidenib isomers
Letemovir Enantiomer
Elagolix-Enantiomer
Tapentadol Diastereomer
Nelarabine α - isomer
Adenosine α - isomer
Atazanavir enantiomer
Ibrutinib Enantiomer
Thiothixene Z-isomer
Gemifloxacin-E-isomer
Methotrexate Enantiomer
Sitagliptin Enantiomer
Acalabrutinib Enantiomer
Melphalan Enantiomer
Scopolamine Enantiomer
Ambrisentan Enantiomer
Netarsudil Enantiomer
Ibrutinib Enantiomer
Linagliptin Enantiomer
Manidipine R & S isomer
Doxepine E & Z isomer
Vilanterol Enantiomer

Popular Nitroso Compounds

Non-Labeled Nitroso Compounds

1-nitroso-1,2,3,6-tetrahydropyridine

3-(4-nitroso-1-oxoisindolin-2-yl)piperidine-2,6-dione

7-nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyrazine

Carvedilol Nitroso Impurity

Desvaleryl Valsartan N-Nitroso Impurity

ethyl)carbamoyl)-3,5-dimethyl-1H-pyrrole-2-carboxylate

Etomidate intermediate Nitroso impurity

Frovatriptan Nitroso Impurity

Lapatinib nitroso impurity

N-(2-(ethyl(nitroso)amino)ethyl)-2,4-dimethyl-1H-pyrrole-3-carboxamide

N-(2-(ethyl(nitroso)amino)ethyl)-5-formyl-2,4-dimethyl-1H-pyrrole-3-carboxamide

N-(2-aminoethyl)-N-ethylnitrous amide

Nebivolol Nitroso impurity

Nitrosamine impurity of Orphenadrine (Mixture of isomers)

Nitroso aryl piperazine

Nitroso Derivative of Prucalopride Impurity A

Nitroso Tamsulosin Impurity (Mixture of isomers)

N-methyl-N-phenethylnitrous amide

N-Nitrosamine Trimetazidine .HCl

N-Nitroso Atenolol Impurity

N-Nitroso Bupropion

N-Nitroso Dabigatran etexilate

N-Nitroso Lumefantrine Impurity

N-Nitroso Mirabegron

N-Nitroso Mirabegron S-Isomer

N-Nitroso N-Desbenzyl Nicardipine Impurity

N-Nitroso N-Desmethyl Zolmitriptan

N-Nitroso Paroxetine

N-Nitroso Ramipril

N-Nitroso Rasagiline

N-Nitroso Rivaroxaban Open-Ring Acid Impurity

N-Nitroso Sertraline

N-Nitroso Silodosin

N-Nitroso Tigecycline

N-Nitroso Varenicline

N-Nitroso Zanubrutinib

N-Nitrosometoprolol

N-Nitroso-N-Desmethyl Nicardipine Impurity

N-Nitrosonortriptyline

Oseltamivir Di-allyl tert-Butyl Nitroso

Oseltamivir tert-Butyl Nitroso

Palbociclib Nitroso Impurity

Relugolix Nitroso Impurity (Mixture of isomers)

Rivaroxaban Nitroso Impurity 2

tert-butyl-4-((2-(ethyl(nitroso)amino)

Vildagliptin Nitroso impurity

Zanubrutinib Nitroso Impurity-1

Zanubrutinib Nitroso Impurity-2

(Z)-N-(2-(ethyl(nitroso)amino)ethyl)-5-((5-fluoro-2-oxoisindolin-3-ylidene)methyl)-2,4-dimethyl-1H-pyrrole-3-carboxamide

Labeled Nitroso Compounds

4-((methyl-d₃)(nitroso)amino)

butanoic acid

(Mixture of isomers)

N | N-bis(ethyl-d₅)nitrous amide

Nitroso aryl piperazine-D₈

Nitroso Nebivolol D₄

N-Nitroso Atenolol-D₅

N-Nitroso Nortriptyline-D₃

N-Nitroso Rasagiline-D₄

N-Nitroso-Tamsulosin D₄

Sitagliptin Nitroso Impurity-D₄

Trimetazidine nitroso D₉ impurity



API LABELED STANDARDS

Acenocoumarol-D5	Diltiazem - D4	Methotrexate - D3	Ribociclib-D8
Acotiamide - D6	Dipyridamole - D20	Metoclopramide - D3	Rivastigmine - D6
Afatinib - D6	Dihydroergotamine D3	Metoprolol - D6	Relugolix D6
Agomelatine - D3 & D6	Domperidone - D6	Metopimazine - D6	Ruxolitinib - D9
Albendazole - D3	Doxazosin - D8	Midodrine - D6	Sacubitril - D4
Alcaftadine-D3	Duloxetine - D3	Milnacipran - D10	Salmeterol - D3
Alfuzosin - D6	Edoxaban-D6	Minoxidil - D10	Sapropterin-D3
Alvimopan - D5	Elagolix - D6	Monomethyl fumarate - D5	Sarpogrelate-D3, D4 & D6
Ambrisentan - D3	Eluglstat - D15	Nadolol-D9	Scopolamine - D3
Apremilast - D3	Eluxadoline - D3	(D) & (L) Nebivolol D4	Selexipag - D6
Atazanavir - D6	Enzalutamide - D3 & D6	Nintedanib - D3	Sildenafil - D3 & D8
Avobenzone - D3	Erlotinib - D6	Nirmatrelvir D9	Sildenafil - D4
Axitinib - D3	Escitalopram oxalate - D3	Octocrylene - D10	Sofosbuvir - D6
Baclofen - D4	Esomeprazole - D3	Olanzapine - D3	Sumatriptan - D6
Binimetinib-D3	Ethacizine - D5	Omeprazole - D3	Tadalafil - D3
Biopterin - D3	Fedratinib - D9	Ondansetron - D3	Tamsulosin - D4
Bosentan - D4	Fingolimod - D4	Osetamivir - D3 & D5	Tasimelepton - D5
Brexiprazole - D8	Fluphenazine - D6	Osimertinib - D6	Tamatinib-D9
Brequinar - D3	Flurbiprofen - D3	Oxaceprol-D3	Tenofovir Alafenamide- D5
Bupropion - D6 & D9	Gefitinib - D3	Palbociclib - D8	Tetrabenazine - D3 & D6
Buspirone - D8	Glasdegib - D4	Paroxetine - D4	Tetrabenazine Desmethyl-D3
Candesartan - D5	Gliclazide - D4	Pazopanib - D3	Tepotinib-13CD3
Carbimazole - D3 & D5	Granisetron - D3	Perospirone - D8	Tiagabine - D5
Carvedilol - D4	Hydroxychloroquine - D5	Phenytoin - D10	Timolol - D9 Maleate
Cibenzoline - D4	Ibrutinib - D5	Phytonadione (E) & (Z) D7	Trandolapril - D5
Cilostazol - D11	Ibuprofen - D3	Pitolisant D10	Ulipristal acetate - D3
Citalopram Hydrobro- mide-D3	Imatinib - D3	Pirfenidone - D3	Ubrogepant D5
Clomiphene Z-isomer-D10	Ivosidenib-D4	Pitofenone - D4	Valsartan - D9
Clomiphene E-Isomer-D10	Ketoprofen - D3	Podophyllotoxin - D3	Velpatasvir - D3
Cyclizine D3	Lacosamide - D3 & D6	Prazosin - D8	Venlafaxine - D4
Cyclosporine - D4	Lasmiditan-D3	Procyclidine-D5	Verapamil - D6
Cyproterone Acetate - D3	Ledipasvir - D6	Propiomazine - D6	Vericiguat - D3
Daclatasvir - D6	Levothyroxine - D3	Promethazine - D6	Vortioxetine - D8
Dapagliflozin - D5	Losartan Azide D4	Propafenone - D5	Viloxazine D5
Darolutamide - D4	Macitentan - D4	Hydroxy Propranolol D7	Warfarin - D5
Dasatinib - D4	Mebeverine acid D5	Quetiapine - D4	Zileuton-D4
Deferasirox - D4	(R) & (S) Manidipine-D4	Raloxifene - D4	(R) & (S)-Tranylcypromine-D5
Desglymidodrine-D6	Mephesisin - D3	Ranolazine - D3 & D8	(R) & (S)-Oxybutynine D10
Diazoxide - D3	Metaxalone - D6	Resiquimod - D5	Verapamil R & S D6
Digoxin - D3	Methimazole - D3	Ritonavir - D6	Nor Verapamil R & S D6



FDA COMPLIANT FACILITY



Isolation > Characterization > Synthesis

IMPURITIES

Target Impurity with
CoA from US-FDA
Compliance Analytical
lab

Deliverables

Crude sample and
HPLC, Mass data
of Target
Impurities

Requirements

Quote for
Feasibility
&
Characterization

Synthetic route
design and
Synthesis of
target impurity

**Isolation
Synthesis**

Feasibility

Isolation of
Target Impurity
(5 mg) through
Preparative
HPLC / SFC

Characterization

Analytical data (1H NMR,
Mass) Structural
Elucidation

Isolation of target quantity
through Preparative
HPLC / SFC

Scale-up decision
Isolation / Synthesis | Quote for Scale-up

DAICEL



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