



Mylan is one of
the world's leading
manufacturers
of high quality
**Active
Pharmaceutical
Ingredients**



Mylan

Better Health
for a Better World

Commercial APIs

Product	U.S. DMF	EDMF / CTD	CEP	JDMF	KDMF	USP	EP	IH	Therapeutic Category
Abacavir Sulfate	✓		✓			✓	✓		Anti Retroviral
Acyclovir	✓		✓	✓	✓	✓	✓		Anti Viral
Alprazolam	✓		✓			✓	✓		Sedative
Apixaban	✓							✓	Anticoagulant
Ambrisentan	✓	✓						✓	Anti Hypertensive
Apremilast	✓							✓	Antirheumatic
Aripiprazole	✓		✓			✓	✓		Anti Psychotic
Armodafinil	✓							✓	CNS Stimulant
Asenapine Maleate	✓	✓						✓	Anti Psychotic
Atazanavir Sulfate	✓	✓						✓	Anti Retroviral
Atomoxetine HCl	✓		✓	✓	✓	✓	✓		Anti Depressant
Atorvastatin Calcium	✓		✓		✓	✓	✓		Antihyperlipidemic
Atovaquone	✓		✓			✓	✓		Anti Malarial
Azilsartan								✓	Anti Hypertensive
Blonanserin				✓				✓	Anti Psychotic
Bosentan	✓	✓		✓				✓	Anti Hypertensive
Canagliflozin	✓							✓	Anti Diabetic
Candesartan Cilexetil	✓		✓	✓		✓	✓		Anti Hypertensive
Carvedilol	✓		✓	✓		✓	✓		Anti Hypertensive
Carvedilol Phosphate	✓							✓	Anti Hypertensive
Celecoxib	✓		✓			✓	✓		Anti Inflammatory
Cetirizine Di HCl	✓		✓			✓	✓		Anti Histamine
Citalopram HBr	✓		✓			✓	✓		Anti Depressant
Citalopram HCl			✓				✓		Anti Depressant
Clarithromycin	✓		✓	✓		✓	✓		Anti Bacterial
Clindamycin Palmitate HCl	✓					✓			Anti Bacterial
Clopidogrel Bisulphate						✓	✓		Antiplatelet
Clozapine	✓		✓			✓	✓		Anti Psychotic
Cobicistat	✓							✓	Anti Retroviral
Daclatasvir Di HCl								✓	Hepatitis C
Darunavir	✓	✓						✓	Anti Retroviral
Deferasirox	✓	✓			✓			✓	Iron Chelator
Desloratadine	✓		✓		✓	✓	✓	✓	Anti Histamine
Desvenlafaxine Succinate	✓	✓				✓		✓	Anti Depressant
Dexlansoprazole	✓	✓			✓			✓	Proton Pump Inhibitor
Dimethyl Fumarate	✓	✓						✓	Multiple Sclerosis
Dipyridamole	✓		✓			✓	✓		Antiplatelet
Dolutegravir Sodium	✓							✓	Anti Retroviral
Duloxetine HCl	✓		✓			✓	✓		Anti Depressant
Efavirenz	✓	✓				✓		✓	Anti Retroviral
Eletriptan HBr	✓	✓		✓				✓	Anti Migraine
Elvitegravir	✓							✓	Anti Retroviral
Empagliflozin	✓							✓	Anti Diabetic
Emtricitabine	✓	✓						✓	Anti Retroviral
Enrofloxacin	✓		✓			✓	✓		Animal Health Product
Enzalutamide	✓							✓	Anti Neoplastic
Epinephrine	✓		✓			✓	✓		Anti Histamine
Escitalopram Oxalate	✓		✓			✓	✓		Anti Depressant
Esomeprazole Magnesium Trihydrate	✓		✓			✓	✓		Proton Pump Inhibitor
Eszopiclone	✓	✓				✓		✓	Sedative
Etoricoxib		✓			✓			✓	Anti Inflammatory

Note : This brochure is NOT AN OFFER for sale by Mylan Laboratories Limited. Products protected under specific patents in certain countries are not offered for sale by Mylan in such countries.



Commercial APIs

Product	U.S. DMF	EDMF / CTD	CEP	JDMF	KDMF	USP	EP	IH	Therapeutic Category
Etravirine	✓							✓	Anti Retroviral
Ezetimibe	✓	✓			✓	✓		✓	Antihyperlipidemic
Febantel			✓				✓	✓	Animal Health Product
Febuxostat	✓	✓		✓				✓	Antigout
Fexofenadine HCl	✓					✓		✓	Anti Histamine
Fingolimod HCl	✓					✓	✓	✓	Multiple Sclerosis
Fluconazole	✓		✓			✓	✓		Anti Fungal
Fluticasone Propionate	✓		✓			✓	✓		Anti Asthmatic
Formoterol Fumarate	✓		✓		✓	✓	✓		Anti Asthmatic
Fosamprenavir Calcium	✓	✓						✓	Anti Retroviral
Frovatriptan Succinate	✓	✓						✓	Anti Migraine
Icatibant Acetate	✓							✓	Hereditary Angioedema
Irbesartan	✓		✓	✓		✓	✓		Anti Hypertensive
Itraconazole	✓		✓	✓		✓	✓		Anti Fungal
Lamivudine	✓		✓			✓	✓		Anti Retroviral
Lansoprazole	✓		✓	✓		✓	✓		Proton Pump Inhibitor
Lanthanum Carbonate	✓	✓		✓				✓	Phosphate Binder
Ledipasvir	✓							✓	Hepatitis C
Lenalidomide	✓	✓			✓			✓	Anti Neoplastic
Letrozole	✓		✓			✓	✓		Anti Neoplastic
Leuprolide	✓					✓		✓	Anti Neoplastic
Levofloxacin	✓	✓		✓		✓		✓	Anti Bacterial
Linagliptin	✓							✓	Anti Diabetic
Lopinavir	✓		✓			✓	✓		Anti Retroviral
Loratadine	✓		✓	✓	✓	✓	✓		Anti Histamine
Losartan Potassium	✓		✓	✓	✓	✓	✓		Anti Hypertensive
Lurasidone HCl	✓					✓		✓	Anti Psychotic
Macitentan	✓							✓	Anti Hypertensive
Mafenide Acetate	✓							✓	Antibiotic
Memantine HCl	✓	✓				✓		✓	Anti Parkinson's
Mirtazapine	✓		✓			✓	✓		Anti Depressant
Modafinil	✓		✓			✓	✓		CNS Stimulant
Montelukast Sodium	✓		✓	✓		✓	✓		Anti Asthmatic
Moxifloxacin HCl			✓			✓	✓		Anti Bacterial
Nadolol			✓			✓	✓		Anti Hypertensive
Octreotide Acetate	✓					✓		✓	Growth Hormone Modulator
Olmесartan Medoxomil	✓		✓	✓		✓	✓		Anti Hypertensive
Oseltamivir Phosphate	✓			✓		✓	✓		Anti Viral
Palbociclib	✓							✓	Anti Neoplastic
Paliperidone	✓	✓				✓		✓	Anti Psychotic
Paliperidone Palmitate	✓							✓	Anti Psychotic
Pantoprazole Sodium	✓		✓			✓	✓		Proton Pump Inhibitor
Parecoxib Sodium								✓	Anti Inflammatory
Paroxetine HCl			✓	✓		✓	✓		Anti Depressant
Pirfenidone	✓							✓	Idiopathic Pulmonary Fibrosis
Plecanatide								✓	Gastrointestinal Agent
Pomalidomide	✓							✓	Anti Neoplastic
Pramipexole DiHCl	✓		✓	✓		✓	✓		Anti Parkinson's
Prasugrel HCl	✓					✓		✓	Antiplatelet
Prasugrel Besylate		✓						✓	Antiplatelet
Pregabalin	✓		✓		✓	✓	✓		Anti Epileptic

✓ Indicates DMF is available for reference as per GDUFA

Note : This brochure is NOT AN OFFER for sale by Mylan Laboratories Limited. Products protected under specific patents in certain countries are not offered for sale by Mylan in such countries.

Commercial APIs

Product	U.S. DMF	EDMF / CTD	CEP	JDMF	KDMF	USP	EP	IH	Therapeutic Category
Proguanil HCl	✓		✓			✓	✓		Anti Malarial
Propafenone	✓		✓			✓	✓		Anti Arrhythmic
Quetiapine Fumarate	✓		✓		✓	✓	✓		Anti Psychotic
Raltegravir Potassium	✓					✓	✓	✓	Anti Retroviral
Rasagiline Mesylate	✓	✓						✓	Anti Parkinson's
Risperidone	✓		✓	✓	✓	✓	✓		Anti Psychotic
Ritonavir	✓		✓			✓	✓		Anti Retroviral
Rivaroxaban								✓	Anticoagulant
Rivastigmine	✓		✓	✓	✓	✓	✓		Anti Alzheimer
Rivastigmine Tartrate	✓		✓		✓	✓	✓		Anti Alzheimer
Rizatriptan Benzoate	✓		✓	✓		✓	✓		Anti Migraine
Rotigotine	✓	✓						✓	Anti Parkinson's
Sacubitril	✓							✓	Anti Hypertensive
Sacubitril Valsartan	✓							✓	Anti Hypertensive
Salmeterol Xinafoate	✓		✓			✓	✓		Anti Asthmatic
Saxagliptin HCl	✓	✓						✓	Anti Diabetic
Sertraline HCl	✓		✓	✓		✓	✓		Anti Depressant
Sevelamer Carbonate	✓	✓						✓	Phosphate Binder
Sildenafil Citrate	✓		✓	✓		✓	✓		Erectile Dysfunction
Sitagliptin HCl								✓	Anti Diabetic
Sitagliptin Phosphate	✓	✓			✓	✓		✓	Anti Diabetic
Sodium ferric gluconate								✓	Iron supplements
Sofosbuvir	✓							✓	Hepatitis C
Sucroferric oxyhydroxide	✓							✓	Phosphate Binder
Sumatriptan Succinate	✓		✓	✓		✓	✓		Anti Migraine
Tadalafil	✓		✓	✓	✓	✓	✓		Erectile Dysfunction
Telmisartan	✓		✓			✓	✓		Anti Hypertensive
Tenofovir Alafenamide Fumarate	✓							✓	Anti Retroviral
Tenofovir Disoproxil Fumarate	✓				✓			✓	Anti Retroviral
Tetrabenazine	✓	✓						✓	Anti Parkinson's
Thio-TEPA	✓	✓				✓		✓	Anti Neoplastic
Ticagrelor	✓							✓	Antiplatelet
Trazodone HCl	✓	✓				✓		✓	Anti Depressant
Valaciclovir	✓		✓	✓		✓	✓		Anti Viral
Valaciclovir Anhydrous				✓		✓		✓	Anti Viral
Valganciclovir	✓	✓				✓		✓	Anti Viral
Valsartan	✓		✓	✓	✓	✓	✓		Anti Hypertensive
Vardenafil HCl			✓				✓	✓	Erectile Dysfunction
Varenicline Tartrate	✓	✓						✓	Smoking Cessation
Velpatasvir								✓	Hepatitis C
Verapamil HCl	✓					✓	✓		Anti Hypertensive
Vilazodone HCl	✓							✓	Anti Depressant
Vildagliptin								✓	Anti Diabetic
Zidovudine	✓		✓			✓	✓		Anti Retroviral
Zofenopril Calcium	✓	✓						✓	Anti Hypertensive
Zolmitriptan	✓	✓				✓	✓	✓	Anti Migraine
Zolpidem Tartrate	✓		✓	✓		✓	✓		Sedative

✓ Indicates DMF is available for reference as per GDUFA

Note : This brochure is NOT AN OFFER for sale by Mylan Laboratories Limited. Products protected under specific patents in certain countries are not offered for sale by Mylan in such countries.



APIs Under Development

Product	Therapeutic Category
Abaloparatide	Osteoporosis
Abametapir	Anti Parasitic
Abemaciclib	Anti Neoplastic
Apalutamide	Anti Neoplastic
Avatrombopag	Antihemorrhagic
Baricitinib	Rheumatoid Arthritis
Betrixaban Maleate	Antithrombotic
Bictegravir Sodium	Anti Retroviral
Bilastine	Anti Histamine
Brexpiprazole	Anti Psychotic
Brigatinib	Anti Neoplastic
Dasatinib	Anti Neoplastic
Deutetrabenazine	Anti Parkinson's
Dextromethorphan HBr	Anti Histamine
Edoxaban Tosylate	Anticoagulant
Efinaconazole	Anti Fungal
Eprosartan	Anti Hypertensive
Garenoxacin Mesilate	Antibiotic
Ibandronate Na	Osteoporosis
Ibrutinib	Anti Neoplastic
Idelalisib	Anti Neoplastic
Lanreotide	Hormone Regulator
Larotrectinib	Anti Neoplastic
Linacotide	Gastrointestinal Agent
Liraglutide	Anti Diabetic
Lumacaftor	Cystic Fibrosis
Maraviroc	Anti Retroviral
Nintedanib Esylate	Idiopathic Pulmonary Fibrosis
Osimertinib	Anti Neoplastic
Ozanimod	Multiple Sclerosis
Pemetrexed Disodium	Anti Neoplastic
Penciclovir	Anti Viral
Regorafenib	Anti Neoplastic
Ribociclib Succinate	Anti Neoplastic
Roxadustat	Antianemic
Rucaparib Camsylate	Anti Neoplastic
Safinamide	Anti Parkinson's
Selexipag	Anti Hypertensive
Semaglutide	Anti Diabetic
Sotagliflozin	Anti Diabetic
Suvorexant	Sedative
Trametinib	Anti Neoplastic
Treprostinil & Treprostinil Diolamine	Anti Hypertensive
Upadacitinib	Rheumatoid Arthritis
Vadadustat	Antianemic
Valbenazine Tosylate	CNS Agent
Venetoclax	Anti Neoplastic
Vortioxetine HBr	Anti Depressant

Note : This brochure is NOT AN OFFER for sale by Mylan Laboratories Limited. Products protected under specific patents in certain countries are not offered for sale by Mylan in such countries.

Mylan API US LLC Portfolio

Product	U.S. DMF	EDMF / CTD	CEP	JDMF	KDMF	USP	EP	IH	Therapeutic Category
Azacitidine	✓							✓	Anti Neoplastic
Azathioprine	✓		✓			✓	✓		Immunosuppressant
Bexarotene	✓							✓	Anti Neoplastic
Bortezomib	✓	✓		✓				✓	Anti Neoplastic
Bromfenac Sodium	✓							✓	Anti Inflammatory
Busulfan	✓		✓			✓	✓		Anti Neoplastic
Carfilzomib								✓	Anti Neoplastic
Cevimeline HCl	✓							✓	CNS Agent
Clofarabine	✓	✓						✓	Anti Neoplastic
Colestipol	✓							✓	Antihyperlipidemic
Disulfiram	✓					✓	✓		Alcohol Antagonist
Dofetilide	✓					✓			Anti Arrhythmic
Droxidopa	✓							✓	Anti Parkinson's
Ethacrynic Acid	✓					✓			Diuretics
Felbamate	✓							✓	Anti Epileptic
Flucytosine	✓					✓			Anti Fungal
Fomepizole	✓					✓			Antidotes
Fondaparinux	✓					✓			Anticoagulant
Miglustat	✓							✓	Enzyme Inhibitor
Molindone HCl	✓					✓			Anti Psychotic
Netupitant	✓							✓	Anti Emetic
Phenoxybenzamine	✓					✓			Anti Hypertensive
Phentolamine Mesylate	✓					✓			Cardiovascular
Plerixafor	✓							✓	Anti Neoplastic
Ponatinib	✓							✓	Anti Neoplastic
Primaquine Phosphate	✓					✓			Anti Neoplastic
Procarbazine	✓					✓			Anti Neoplastic
Regadenoson	✓							✓	Diagnostic Agent
Romidepsin								✓	Anti Neoplastic
Sincalide	✓							✓	Diagnostic Agent
Sodium Nitroprusside	✓					✓			Anti Hypertensive
Sugammadex	✓							✓	CNS Agent
Trientine HCl	✓					✓			Antidotes
Trifluridine								✓	Anti Viral
Zileuton	✓					✓			Anti Inflammatory

✓ Indicates DMF is available for reference as per GDUFA

Note : This brochure is NOT AN OFFER for sale by Mylan Laboratories Limited. Products protected under specific patents in certain countries are not offered for sale by Mylan in such countries.



Our state-of-the-art API facilities are frequently inspected by the Indian FDA and multiple global regulatory authorities.

Unit 1	Hyderabad
U.S. FDA	2018, 2016, 2013, 2011, 2009, 2007
AGES (Austria)	2019, 2016, 2011, 2008
WHO	2015, 2012, 2011, 2006
EDQM	2015
AFM	2010
MFDS	2011
COFEPRIS	2014
PMDA	2019, 2017

Unit 2	Hyderabad
U.S. FDA	2018, 2016, 2013, 2011, 2009, 2006, 2004
WHO	2016, 2013, 2005
EDQM	2009
AFM	2008
ANVISA	2013, 2011
COFEPRIS	2014
PMDA	2019

Unit 7	Hyderabad
U.S. FDA	2016, 2015, 2012, 2009, 2005, 2001
AGES (Austria)	2019, 2015, 2011, 2008
BGV (Germany)	2010, 2006
TGA	2004, 1999
MHRA	1998
AFM	2006
MFDS	2011
ANVISA	2015, 2013, 2011
COFEPRIS	2014
PMDA	2017

Unit 8	Visakhapatnam
U.S. FDA	2019, 2018, 2017, 2015, 2012, 2009, 2006, 2002
AGES (Austria)	2015, 2011, 2008
WHO	2017, 2014, 2011, 2009, 2008, 2007, 2005
BGV (Germany)	2013
EDQM	2010
SWISSMEDIC	2010
AFM	2007
MFDS	2011
COFEPRIS	2014
ANVISA	2019, 2017
PMDA	2019, 2017



Unit 9	Visakhapatnam
U.S. FDA	2015, 2012
AGES (Austria)	2011
WHO	2017, 2015, 2011
AFM	2012
MFDS	2018
TGA	2013
TPD (Canada)	2019

Unit 10	Visakhapatnam
U.S. FDA	2018, 2015, 2013
AGES (Austria)	2015
WHO	2015
MFDS	2016
ANVISA	2017

Unit 11	Mumbai
U.S. FDA	2017, 2015, 2012, 2007, 2003
AGES (Austria)	2018, 2016
AFM	2011
MFDS	2011
TGA	2011
PMDA	2018

Mylan API US LLC	USA
U.S. FDA	2017, 2016, 2013, 2011, 2010, 2008





Mylan Laboratories Limited

Plot No. 564/A/22, Road No. 92,
Jubilee Hills, Hyderabad -500096
Telangana, India

Tel: +91.40.30866666, 23550543

Fax: 30866699

Email: apisales@mylan.in

www.mylan.in

GIN: U24231TG1984PLC005146



Mylan

Better Health
for a Better World