

PRODUCT NAME	DMF						EDA White-list	THERAPEUTIC CATEGORY
	US	CEP	EU	BR	CN	KDMF		
Aminocaproic acid	✓	—	—	—	✓	—	—	Anti-Fibrinolytic agent
Amorolfine	—	✓	—	—	—	—	—	Anit-Fungal
Apixaban	✓	—	—	—	—	—	✓*	Anti-Coagulant
Bedaquiline Fumarate	—	—	—	—	—	—	—	Anti-Biotic
Bempedoic acid	✓	—	—	—	✓	—	✓	Lipid-Lowering Agents
Bilastine	—	—	—	—	—	—	—	Antihistamine
Brivaracetam	✓	✓#	—	—	—	—	✓*	Anti-Convulsant
Bucillamine	✓	—	—	—	—	—	—	Anti-inflammatory
Cariprazine HCl	✓	—	—	—	—	—	—	Anti-Psychotic
Cenobamate	✓	—	—	—	—	—	—	Anti-Convulsant
Crisaborole	✓	—	—	—	—	—	—	Anti-inflammatory
Dabigatran Etxilate Mesylate	✓	—	✓	—	—	—	—	Anti-Coagulant
Daclatasvir Dihydrochloride	—	—	—	✓	—	—	—	Hepatitis C
Dapagliflozin Amorphous	✓	—	—	—	—	—	—	Anti-Diabetic
Dapagliflozin Propanediol	—	—	—	—	—	—	✓*	Anti-Diabetic
Dapoxetine HCl	—	—	✓	—	—	✓	—	Anti-Depressant
Dimethyl Fumarate	✓	—	—	—	—	—	—	Multiple Sclerosis
Dithranol	—	✓	✓	—	—	—	—	Anti-Psoriatic
Divalproex Sodium	✓	—	✓	✓	—	—	—	Anti-Convulsant
Docosanol	—	—	—	—	—	—	—	Anti-Viral
D-Penicillamine	✓	—	—	—	—	—	—	Anti-Rheumatic
Eberconazole Nitrate	—	—	✓	—	—	—	—	Anti-Fungal
Edoxaban Tosylate	✓	—	—	—	—	—	—	Anti-Coagulant
Elagolix Sodium	✓	—	—	—	—	—	—	GnRH antagonist
Eletriptan hydrobromide	—	—	✓	—	—	—	—	Anti-Migraine
Eltrombopag Olamine	✓	—	—	—	—	—	✓*	Thrombopoietin receptor
Empagliflozin	✓	—	—	—	—	—	✓*	Anti-Diabetic
Favipiravir	✓	—	✓	—	—	—	—	Anti-Viral
Fenticonazole Nitrate	—	✓	—	✓	—	—	—	Anti-Fungal
Finerenone	✓	—	—	—	—	—	✓*	Cardiovascular
Gabapentin	✓	✓	—	✓	✓	—	✓*	Anti-Convulsant
Isavuconazonium Sulfate	✓	—	—	—	—	—	—	Anti-Fungal
Lamotrigine	—	—	—	—	—	—	—	Anti-Psychotic
Linagliptin	✓	—	—	—	—	—	✓*	Anti-Diabetic
Linezolid Form I	—	—	✓	—	—	—	—	Anti-Bacterial
Linezolid Form II	✓	—	✓	✓	✓	—	✓	Anti-Bacterial
Linezolid Form III	✓	—	—	—	—	—	—	Anti-Bacterial
Lornoxicam	—	—	✓	—	✓	—	—	Anti-Inflammatory
Luliconazole	—	—	—	—	—	—	—	Anti-fungal
Lumateperone Tosylate	—	—	—	—	—	—	✓*	Anti-Psychotic
Magnesium Valproate	—	—	—	—	—	—	—	Anti-Convulsant
Mebendazole Form-A/C	✓	—	—	—	—	—	—	Anti-fungal
Midodrine Hydrochloride	✓	—	—	—	—	—	—	Anti-hypotensive
Mirabegron	—	—	—	—	—	—	—	Over Active Bladder
Mirogabalin Besylate	—	—	—	—	—	—	✓	Anti-Convulsant
Molnupiravir	✓	—	—	—	—	—	—	Anti-Viral
Nabilone	—	—	—	—	—	—	—	Antiemetic
Nirmatrelvir	✓	—	—	—	—	—	—	Anti-Viral
Obeticholic Acid	✓	✓	—	—	—	—	—	Semi-Synthetic Bile Acid
Oxiconazole Nitrate	—	—	—	—	—	—	—	Anti-Fungal
Ozenoxacin	—	—	—	—	—	—	—	Anti-Biotic
Phenylamidol Hydrochloride	—	—	—	—	—	—	—	Muscle Relaxant
Pirfenidone	✓	✓	—	—	—	—	—	Anti-Fibrotic

PRODUCT NAME	DMF						EDA White-list	THERAPEUTIC CATEGORY
	US	CEP	EU	BR	CN	KDMF		
Prasugrel Hydrochloride	—	—	—	—	—	—	—	Anti-Platelet
Pregabalin	✓	✓	—	✓	✓	✓	—	Anti-Convulsant
Quetiapine Fumarate	—	—	—	—	—	—	—	Anti-Psychotic
Rasagiline Mesylate	—	—	—	—	—	—	—	Anti-Parkinson
Rasagiline Tartrate	—	—	—	—	—	—	—	Anti-Parkinson
Resmetirom	—	—	—	—	—	—	✓*	NASH
Rifapentine	—	—	—	—	—	—	✓	Anti-tuberculosis
Rifaximin	✓	✓	—	✓	—	✓	✓	Anti-Biotic
Rivaroxaban	✓	✓	—	—	—	—	✓*	Anti-Coagulant
Rosuvastatin Calcium	—	✓#	—	—	—	—	✓*	Antilipemic
Roxadustat	—	—	—	—	—	—	—	Anti-Anemia
Safinamide Mesylate	✓	—	✓	✓	—	✓	—	Anti-Parkinson
Sertaconazole Nitrate	—	—	—	—	—	—	—	Anti-Fungal
Sitagliptin Phosphate	✓	✓	—	—	—	—	✓*	Anti-Diabetic
Sodium Valproate	—	✓	—	✓	✓	—	—	Anti-Convulsant
Sofosbuvir	—	—	—	—	—	—	—	Anti-Viral
Solifenacin Succinate	✓	✓	—	—	—	✓	✓*	Urinary Disease
Sotagliflozin	—	✓	—	—	—	—	✓*	Cardiovascular
Tafamidis Free Base	—	—	—	—	—	—	—	Cardiovascular
Tafamidis Meglumine	✓	—	—	—	—	—	—	Cardiovascular
Tapinarof	✓	—	—	—	—	—	—	Anti-inflammatory
Tedizolid Phosphate	—	—	—	—	—	—	—	Anti-Bacterial
Teriflunomide	✓	✓	—	—	—	—	✓	Multiple Sclerosis
Tioconazole	—	✓	—	✓	—	—	—	Anti-Fungal
Tofacitinib Citrate	—	—	—	—	—	—	—	Janus kinase (JAK) inhibitor
Upadacitinib	✓	—	—	—	✓	—	✓*	Immunosuppressant
Valproic Acid	✓	✓	—	✓	✓	—	—	Anti-Convulsant
Vildagliptin	✓	—	—	—	—	—	✓	Anti-Diabetic
Vonoprazan Fumarate	✓	—	—	✓	✓	✓	✓	Gastrointestinal (GI)
Zileuton	✓	—	—	—	—	—	—	Anti-Inflammatory

API PRODUCT UNDER DEVELOPMENTS

PRODUCT NAME	SAMPLES	TECH PACK AVAILABILITY	STATUS	THERAPEUTIC CATEGORY
Amitriptyline HCL	—	—	Under Development	Anti-Depressant
Atogepant	✓	✓	Under Development	Anti-Migrane
Canagliflozin	✓	—	Under Development	Anti-Diabetic
Clomipramine	—	—	Under Development	Anti-Depressant
Fezolinetant	—	—	Under Development	Women's Health
Hydrochlorothiazide	—	—	Under Development	Hypertension
Imipramine	—	—	Under Development	Anti-Depressant
Letermovir	—	—	Under Development	Anti-Viral
Nortriptyline HCL	—	—	Under Development	Anti-Depressant
Rimegepant Sulfate	✓	✓	Under Development	Anti-Migrane
Tegoprazan	✓	✓	Under Development	Gastrointestinal (GI)
Tranexamic acid	—	—	Under Development	Antifibrinolytic
Xanomeline Tartrate	✓	✓	Under Development	Anti-Psychotic

✓* Under Filing

✓# Under review (EDQM)

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