

ACTIVE PHARMACEUTICAL INGREDIENTS (API) LIST

API	Therapeutic Category	US (DMF)	Europe (CEP/ASMF)	Canada	Brazil	China/ Japan	ROW
Acamprosate Calcium	Anti-Alcoholism	√	√*	WIP	-	-	-
Acetazolamide	Anti-Glaucoma	√	√	√	-	-	√
Adenosine Base	Anti-Arrhythmic	√	√	-	-	CDMF	√
Amiodarone HCl	Anti-Arrhythmic	√	√*	-	-	-	√
Arsenic Trioxide	Oncology	√	ASMF	√	-	-	√
Azacitidine Base	Oncology	-	ASMF-WIP	-	-	-	-
Benazepril HCl	Anti-Hypertensive	√	-	-	-	-	-
Bendamustine HCl	Oncology	√	-	-	-	JDMF	√
Buspirone HCl	Anti-Anxiety	√	-	-	-	-	√
Busulfan	Oncology	√	√	√	√	-	√
Carmustine	Oncology	√	√	√	-	-	√
Cyclophosphamide	Oncology	√	√	-	-	-	√
Desvenlafaxine Base	Anti-Depressant	-	-	-	-	-	√
Dexketoprofen Trometamol	NSAID	-	ASMF	-	-	-	√
Dexmedetomidine HCl	Anti-Anxiety	√	-	-	√	-	√
Diflunisal	NSAID	√	-	-	-	-	-
Dydrogesterone	Hormone Therapy	-	√*	-	-	-	√
Eribulin Mesylate	Oncology	√	ASMF	√	√	-	√
Eszopiclone	Sedative/ Hypnotic	√	-	√	WIP	-	√
Felbamate	Anti-Convulsant	√	-	-	-	-	-
Ferric Carboxymaltose	Haematinic	WIP	ASMF-WIP	-	-	-	√
Ferrous Ascorbate	Haematinic	-	-	-	-	-	-
Fingolimod HCl	Immuno-Modulator	√	√	√	-	-	√
Flecainide Acetate	Anti-Arrhythmic	√	√	√	-	-	√
Foscarnet Sodium	Anti-Viral	√	√	-	-	-	-
Hydroxyzine HCl	Anti-Anxiety	√	-	-	-	-	-
Hydroxyzine Pamoate	Anti-Anxiety	√	-	-	-	-	-
Ibutilide Fumarate	Anti-Arrhythmic	√	-	-	-	-	-
Iron (III) Hydroxide Polymaltose complex	Haematinic	-	-	-	-	-	√
Iron Sucrose Solution	Haematinic	√	-	-	-	-	√
Isoproterenol HCl (Isoprenaline HCl)	Bronchodilator	√	√	√	-	-	√
Leflunomide	Immuno-Modulator	√	√	-	√	-	√
Levosimendan	Cardiovascular	WIP	ASMF	-	-	-	√
Mefloquine HCl	Anti-Malarial	-	-	-	-	-	√
Melphalan HCl	Oncology	√	ASMF	√	√	-	√
Midodrine HCl	Anti-Hypertensive	√	ASMF	√	-	-	√
Milrinone Base	Anti-Hypertensive	√	ASMF	√	√	-	√
Mycophenolate Mofetil	Immuno-Modulator	√	√	√	√	-	√

COMMERCIAL APIs

API	Therapeutic Category	US (DMF)	Europe (CEP/ASMF)	Canada	Brazil	China/ Japan	ROW
Nefopam HCl	NSAID	-	ASMF	-	-	-	√
Neostigmine Methylsulfate	Anti-Cholinesterase	√	-	√	-	-	√
Paliperidone Base	Anti-Psychotic	√	ASMF	√	-	-	√
Palonosetron HCl	Anti-Emetic	√	ASMF	-	-	-	√
Pentamidine Isethionate	Anti-Microbial	√	√	√	-	-	√
Promethazine HCl	Antihistaminic agent	√	√*	-	-	-	√
Propofol	Anaesthetic	√	√	√	WIP	-	√
Rizatriptan Benzoate	Anti-Migraine	√	√	√	-	-	√
Ropivacaine HCl	Anaesthetic	√	√	-	-	-	√
S (-) Amlodipine Besilate	Anti-Hypertensive	-	-	-	√	-	√
S (-) Pantoprazole Sodium	Gastrointestinal agent	-	-	-	-	-	√
Tapinarof	Anti-Psoriasis	√	-	-	-	-	WIP
Thiotepa	Oncology	√	-	-	-	-	√
Treprostinil Base	Anti-Hypertensive	√	ASMF	√	-	-	√
Trientine HCl	Wilson's Disease	√	ASMF	√	-	-	√
Trimethobenzamide HCl	Anti-Emetic	√	-	-	-	-	-
Zoledronic Acid	Bone Disease	√	√	√	-	CDMF	√

UNDER DEVELOPMENT APIs

API	Therapeutic Category
Apixaban	Cardiovascular
Estetrol monohydrate	Hormone Therapy
Ferumoxytol	Haematinic
Lurbinectedin	Oncology
Ponatinib HCl	Oncology
Relugolix	GnRH antagonist (Oral)
Semaglutide	Anti-Diabetic/ Anti-Obesity

√* indicates CEP filed but not yet approved

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