



Innovating Chemistry for Life - Health, Happiness & Harmony



Global Regulatory Filings

Our DMF & CEP Approvals

Active Pharmaceutical Ingredients • Worldwide filing status

36

Active
US DMFs

28

Valid
CEPs

59

APIs with
regulatory filings

20+

Global markets
with filings

FILING STATUS

APIs – Worldwide Regulatory Filings

Filing status of 59 APIs by market.

	PRODUCT	THERAPEUTIC CLASS	USA	EUROPE		CANADA	CHINA	KOREA	JAPAN	TAIWAN	BRAZIL	AUSTRALIA	ROW
			DMF	CEP	ASMF								
A	Allopurinol	Anti-Gout	✓	✓		✓	✓	✓	✓	✓	🟡		✓
B	Benzotropine Mesylate	Anti-Parkinson	✓										
	Bisoprolol Fumarate	Anti-Hypertensive		✓							🟡		✓
C	Carisoprodol	Anxiolytic	✓							✓			
	Choline Fenofibrate	Anti-Hyperlipidemic	✓				✓	✓					
	Clofazimine	Anti-Mycobacterial	✓	✓					✓				✓
	Cupric Sulfate	Vitamins & Supplements	✓										
D	Dapagliflozin	Anti-Diabetic	✓		✓								
	Desethyloxybutynin Hydrochloride	Anti-Muscarinic	✓										
	Divalproex Sodium	CNS / Anti-Convulsant	✓		✓	✓		✓			✓		✓
E	Efinaconazole	Anti-Fungal	✓					✓					
F	Fenofibrate	Anti-Hyperlipidemic	✓	✓		✓		✓		✓	✓	✓	✓
	Fenofibric Acid	Anti-Hyperlipidemic	✓										
	Fospropofol Disodium	Anesthetic	✓										
G	Glycopyrrolate Tosylate	Anti-Cholinergic	✓										
	Glycopyrronium Bromide / Glycopyrrolate	Anti-Cholinergic	✓	✓		✓	✓	✓					✓
I	Isoproterenol Hydrochloride / Isoprenaline Hydrochloride	Adrenergic	✓	✓									
L	Levomethadone Hydrochloride	Opioid Abstinence Syndrome		✓									
	Lidocaine Base	Anesthetic	✓	✓						✓			
	Lidocaine Hydrochloride	Anesthetic	✓	✓						✓			
	Linagliptin	Anti-Diabetic	✓		✓	✓		✓			✓		✓
M	Manganese Sulfate	Vitamins & Supplements	✓										
	Meprobamate	Anxiolytic	✓										
	Metformin Hydrochloride	Anti-Diabetic	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓
	Metformin Hydrochloride (Process II)	Anti-Diabetic	✓	✓		✓	✓	✓			✓		✓
	Metformin Hydrochloride + 0.5% Aerosil	Anti-Diabetic						🟡					
	Metformin Hydrochloride + 1% Aerosil	Anti-Diabetic						🟡					
	Methadone Hydrochloride	Opioid Abstinence Syndrome		✓									
	Methylphenidate Hydrochloride	CNS / Anti-Convulsant		✓									
	Methylphenidate Hydrochloride (Process II)	CNS / Anti-Convulsant		✓							🟡		
	Methylphenobarbital	CNS / Anti-Convulsant		✓									

KEY: ✓ Filed / registered 🟡 Submitted / under review

ROW = rest of world • Subject to change

	PRODUCT	THERAPEUTIC CLASS	USA	EUROPE			CANADA	CHINA	KOREA	JAPAN	TAIWAN	BRAZIL	AUSTRALIA	ROW
			DMF	CEP	ASMF									
N	Neostigmine Methylsulfate	Cholinergic	✓	✓				✓						✓
	Norepinephrine Bitartrate	Adrenergic	✓	✓			✓	✓			✓	✓		✓
O	Oxiconazole Nitrate	Anti-Fungal	✓											
	Oxybutynin Hydrochloride	Anti-Muscarinic	✓	✓							✓			✓
	Oxybutynin Hydrochloride (Process II)	Anti-Muscarinic		✓			✓			✓		✓		
P	Pentobarbital Sodium	CNS / Anti-Convulsant		🟡										
	Phenobarbital	CNS / Anti-Convulsant	✓	✓			✓				✓	✓		✓
	Phenobarbital Sodium	CNS / Anti-Convulsant	✓		🟡									✓
	Phenytoin Base	CNS / Anti-Convulsant		✓								✓		
	Phenytoin Sodium	CNS / Anti-Convulsant	✓	✓	✓	✓	✓	✓						✓
	Potassium Acetate	Vitamins & Supplements	✓											
	Propofol	Anesthetic		✓								✓		✓
R	R-Oxybutynin Hydrochloride	Anti-Muscarinic	✓				✓							
	Riboflavin Phosphate Sodium Salt	Vitamins & Supplements		✓										
S	Sacubitril / Valsartan	Angiotensin Receptor Nepriylsin Inhibitor	✓		🟡	🟡			✓		✓	✓	✓	✓
	Selenious Acid	Vitamins & Supplements	✓											
	Sitagliptin Hydrochloride Monohydrate (Process I)	Anti-Diabetic			✓				✓					✓
	Sitagliptin Hydrochloride Monohydrate (Process II)	Anti-Diabetic			🟡									✓
	Sitagliptin Phosphate Monohydrate (Process I)	Anti-Diabetic							✓					✓
	Sitagliptin Phosphate Monohydrate (Process II)	Anti-Diabetic	✓	✓		✓			🟡		✓			✓
	Sodium Valproate	CNS / Anti-Convulsant		✓								🟡		
	Succinylcholine Chloride	Neuromuscular Blocking Agent	✓							✓				
	Suxamethonium Chloride (Process II)	Neuromuscular Blocking Agent		🟡										
	Tilidine Hydrochloride Hemihydrate	Opioid Abstinence Syndrome		🟡										
V	Valproic Acid	CNS / Anti-Convulsant		✓							✓	🟡		✓
	Valsartan	Anti-Hypertensive	✓	✓										
	Vildagliptin	Anti-Diabetic			✓		✓	✓	✓	✓	✓	✓	✓	✓
X	Xipamide	Diuretic			✓									✓