



# GRANULES

## ACTIVE PHARMACEUTICAL INGREDIENTS (APIs)

Product	Therapeutic Category	Pharmacopeia Grade	Regulatory Filings/DMF Availability						
			TP	ODMF	US	EU	CEP	Korea	Canada
Paracetamol / Acetaminophen	Analgesic, Antipyretic	Ph.Eur & USP	✓	✓	✓	✓	✓	✓	✓
Metformin HCl	Anti-diabetic	Ph.Eur & USP	✓	✓	✓	✓	✓	✓	✓
Ibuprofen	Analgesic	Ph.Eur & USP	✓	✓	✓	✓	✓	✓	✓
Guaifenesin	Mucolytic	Ph.Eur & USP	✓	✓	✓	✓	✓	✓	✓
Methocarbamol	Muscle Relaxant	USP	✓	✓	✓	✓	✓	✓	✓
Fluconazole	Antifungal	Ph.Eur/ USP	✓	✓	✓	✓#	✓	✓	✓#
Cetirizine Dihydrochloride	Antihistamine	Ph.Eur/USP	✓	✓	✓	✓#	✓	-	✓
Levocetirizine Dihydrochloride	Antihistamine	IH	✓	✓	✓	✓	-	✓	-
Losartan Potassium	Antihypertensive	Ph.Eur/USP	✓	✓	✓	✓#	✓	✓	-
Pirfenidone	Anti-fibrotic	IH & Ph.Eur	✓	✓	✓	-	✓	-	-

\* DMF filing in process

# CEP extended to European countries & Other EDQM observers



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Rifaximin	Anti-infective	Ph.Eur/IH	✓	✓	-	✓	✓	-	-
Abacavir Sulfate	Antiretroviral	Ph.Eur/USP	✓	✓	*	-	✓	-	-
Pantoprazole Sodium Sesquihydrate	Anti-ulcerative	Ph.Eur/ USP	✓	✓	-	✓#	✓	-	-
Atazanavir Sulfate	Antiretroviral	IH	✓	✓	*	✓	-	-	-
Gliclazide	Anti-diabetic	Ph.Eur	✓	✓	-	-	✓	-	-
Fexofenadine Hydrochloride	Antihistamine	Ph.Eur/ USP	✓	✓	✓	-	-	-	-
Dimethyl Fumarate	Multiple sclerosis	IH	✓	✓	✓	-	-	-	-
D-Penicillamine	Chelating agent	Ph.Eur/ USP	✓	✓	✓	-	-	-	-
Tenofovir Disoproxil Succinate	Antiretroviral	IH	✓	✓	-	✓	-	-	-
Olmesartan Medoxomil	Antihypertensive	Ph.Eur/IH	✓	✓	-	-	-	-	-

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Omeprazole Magnesium	Anti-ulcerative	USP	✓	✓	*	-	-	-	-
Dabigatran Etexilate Mesylate	Anticoagulant	IH	✓	-	-	-	-	-	-
Darunavir Amorphous	Antiretroviral	IH	✓	-	-	-	-	-	-
Delafloxacin	Antibiotic	IH	✓	-	-	-	-	-	-
Eltrombopag	Anti-Thrombocytopenic	IH	✓	-	-	-	-	-	-
Iopromide	Contrast Agent	USP/ Ph.Eur	✓	-	-	-	-	-	-
Itraconazole	Antifungal	USP	✓	-	-	-	-	-	-
Lurasidone Hydrochloride	Antipsychotic	USP	✓	-	-	-	-	-	-
Metoprolol Succinate	Antihypertensive	USP	✓	-	-	-	-	-	-
Posaconazole	Antifungal	IH	✓	-	-	-	-	-	-

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Prasugrel Hydrochloride	Antiplatelet	USP	✓	-	-	-	-	-	-
Pramiracetam	Nootropic	IH	✓	-	-	-	-	-	-
Propranolol Hydrochloride	Antianginal	Ph.Eur/ USP	✓	-	-	-	-	-	-
Rebamipide	Anti-ulcerative	JP	✓	-	-	-	-	-	-
Sevelamer	Phosphate binder	USP	✓	-	-	-	-	-	-
Teneligliptin	Anti-diabetic	IH	✓	-	-	-	-	-	-
Tenofovir Alafenamide Fumarate	Antiretroviral	IH	✓	-	-	-	-	-	-
Vigabatrin	Anticonvulsant	USP	✓	-	-	-	-	-	-

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