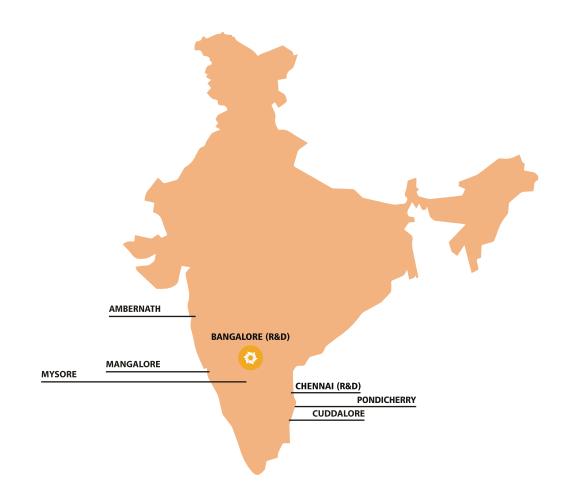
FACILITY GMP AUDITS / COMPLIANCE



AUTHORITY	AMBERNATH	PONDICHERRY	CUDDALORE	MANGALORE
USFDA	2013, 2019	1990, 1996, 2000, 2005, 2009, 2013, 2015, 2017, 2020	1999, 2002, 2007, 2010, 2014, 2017, 2019	2012, 2015, 2018, 2020
EDQM	2017	2007, 2014	2003, 2014, 2017	2017
AGES (Austria)		2007		
KFDA (Korea)		2012, 2017	2012	2018
EU-GMP (Danish)		2008, 2019	2008	
WHO (Geneva)			2012, 2016	2009, 2011, 2014, 2018
MHRA		2017	2017	
Cofepris (Mexico)		2013, 2015	2013, 2014, 2015	
TGA (Australia)			1998	2011, 2013
PMDA (Japan)		2007	2017	



GENERIC APIs

Commercialised



PRODUCT	THEREPEUTIC CATEGORY	USDMF	СЕР	EDMF	WHO	JAPAN	CANADA	KOREA	AUSTRALIA	NEW ZEALAND	CHINA	FACILITY
Aprepitant Form I	Antiemetic	✓										С
Bumetanide (Inj)	Loop Diuretic	✓										С
Cinacalcet hydrochloride	Calcimimetic agent	✓						✓				Р
Citicoline Sodium	Neuro Protective											М
Cycloserine	Antitubercular	✓			✓							С
Colchicine	Antigout agent	✓										М
Disulfiram	Chronic Alcoholism	✓	✓									М
Edaravone	Amyotropic lateral sclerosis	✓										М
Efinaconazole	Antifungal	✓										Α
Ethacrynic acid	Cardiovascular Agent	✓										Р
Etomidate	Anesthetics	✓										М
Felbamate	Anticonvulsant	✓										М
Flecainide Acetate	Anti-arrhythmic agent	✓										М
Gabapentin	Anticonvulsant	✓	✓				✓	✓				С
Hydralazine hydrochloride	Antihypertensive	✓	✓									М
Ibuprofen	Anti-inflammatory	✓	✓			✓	✓				✓	Р
S-Ibuprofen	Anti-inflammatory	✓		✓				✓				Р
Ibuprofen sodium dihydrate	Anti-inflammatory	✓		✓					✓	✓		P and C
Ibuprofen Lysine	Anti-inflammatory			✓								Р

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- P Pondicherry

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PRODUCT	THEREPEUTIC CATEGORY	USDMF	СЕР	EDMF	WHO	JAPAN	CANADA	KOREA	AUSTRALIA	NEW ZEALAND	CHINA	FACILITY
Imiquimod	Topical anti -infectives	✓							✓			М
Labetalol hydrochloride	Anti-hypertensive	✓										М
Lanthanum arbonate Octahydrate	For the treatment of Hyperphosphatemia					✓						С
Lanthanum arbonate Tetrahydrate	For the treatment of Hyperphosphatemia					✓						С
Levetiracetam	Antiepileptic	✓	✓					✓				C and A
Lurasidone hydrochloride	Antipsychotic	✓										Р
Mesna	Antineoplastic detoxifying agent	✓	✓									М
Mefenamic acid	Anti-inflammatory	✓	✓									Α
Methoxsalen	Antipsoriatic	✓										M
Methohexital	Anesthetics	✓		✓								С
Mirabegron	OAB Treatment	✓										С
Mycophenolate Mofetil	Immunosuppressant	✓										А
Nizatidine	Antiulcerative	✓	✓			✓	✓	✓				С

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GENERIC APIs

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PRODUCT	THEREPEUTIC CATEGORY	USDMF	CEP	EDMF	WHO	JAPAN CANADA	KOREA	AUSTRALIA	NEW ZEALAND	CHINA	FACILITY
Obeticholic acid	Bile acid Analogue	✓									С
Olanzapine Form I	Antipsychotic	✓	✓								С
Oseltamivir phosphate	Antiviral	✓		✓	✓		√				М
Patiromer	Hyperkalaemia	✓									С
Pitavastatin calcium	Antihyperlipoproteinemic	✓				✓	✓			✓	С
Pentoxifylline	Hemorrheologic agent		√								А
Praziquantel	Anthelmintic	✓			✓	✓					Μ
Ranitidine hydrochloride Form II	Antiulcer	✓	✓			✓					C
Sapropterin	Phenylalanine reducer	✓									C and A
Sevelamer carbonate	Hypophosphatemic agent	✓									С
Sevelamer hydrochloride	Hypophosphatemic agent	✓				✓					С
Succinylcholine chloride	Skeletal muscle relaxant	✓	✓			✓					М
Zileuton	Anti-Asthmatic	✓									А

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General Product List

In Development/Development

Products	Therapeutic Category
Brivaracetam	Antiepileptic
Buspirone HCL	Anxiolytic
Carbidopa	Antihyperlipidemic
Colesevelam	Antihyperlipidemic
Erythromycin Ethyl Succinate	Antibacterial
Edoxaban Tosylate	Anticoagulant
Favipiravir	Antiviral
Levodopa	Antiparkinson's
Mebendazole	Anthelmintic
Mesalamine	NSAID
Migalastat HCl	Fabry Disease
Mycophenolate Sodium	Immunosuppressant
Naproxen Base	Anti-inflammatory
Naproxen Sodium	Anti-inflammatory
Safinamide Mesylate	Anti-Parkinson
Sertraline HCL	Antidepressant
Sucroferric Oxyhydroxide (USDMF Filed)	Chronic Kidney Disease
Sugammadex Sodium (USDMF Filed)	Neuromuscular
Tranexamic acid	Antifibrinolytic

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