



MAITHRI

# MAITHRI DRUGS PRIVATE LIMITED

**2022 - 23**  
**API PRODUCT LIST**

## APIs with NCE EXCLUSIVITY

PRODUCT	US Filing Date (NCE-1)	EU Filing Date (DE-2)	Tech pack	DMF						Therapeutic Category
				US	EU	CEP	CA	CH	Kore	
Abrocitinib	14-Jan-26	09-Dec-29	★							Atopic dermatitis
Avacopan	07-Oct-25	11-Jan-30	★							Antineutrophil Cytoplasmic Antibody
Benvitimod /Tapinarof	24-May-26	Not Approved	★							Psoriasis vulgaris
Cabotegravir	21-Jan-25	17-Dec-28	★							Antiretroviral
Cenobamate	10-Mar-24	26-Mar-29	★							Partial-onset seizures
Daridorexant	07-Jan-26	29-Apr-30	★							Insomnia
Esketamine Hcl	05-Mar-23	18-Dec-27	✓							Antidepressant
Fenfluramine	25-Jun-23	19-Dec-28	✓	✓						Antiepileptics
Finerenone	09-Jul-25	Not Approved	★							Chronic kidney disease (CKD)
Linzagolix	Not Approved	16-Dec-29	★							Uterine fibroids
Maribavir	23-Nov-25	Not Approved	★							Post-transplant CMV infection
Mavacamten	28-Apr-26	Not Approved	★							Hyper trophic cardiomyopathy (HCM)
Mitapivat	17-Feb-26	Not Approved	★							Hemolytic anemia
Ozanimod	25-Mar-24	20-May-28	✓	✓						Relapsing Multiple Sclerosis
Revefenacin	09-Nov-22	Not Approved	★							Chronic obstructive pulmonary disease
Roxadustat	Not Approved	18-Aug-29	✓	✓						Antianaemics
Siponimod	26-Mar-23	13-Jan-28	✓	✓						Multiple Sclerosis (MS)
Tegoprazan	Not Approved	Not Approved	★							Gastroesophageal reflux disease
Trifarotene	04-Oct-23	Not Approved	✓							Acne vulgaris
Vericiguat	20-Jan-25	16-Jul-29	★							Chronic heart failure
Viloxazine hcl	02-Apr-25	Expired	✓							Deficit hyperactivity disorder
Vonoprazan Fumarate	03-May-26	Not Approved	✓							Gastroduodenal ulcer and reflux esophagitis

## APIs with NCE EXPIRED

PRODUCT	EU Filing Date (DE-2)	Tech pack	DMF						Therapeutic Category
			US	EU	CEP	CA	CH	Kore	
Adapalene	Expired	✓							Antiacne
Besifloxacin Hydrochloride	Not approved	✓	✓						Antibacterials
Brimonidine Tartrate	Expired	✓	✓		✓				Antiglaucoma
Brinzolamide	Expired	★							Antiglaucoma
Carbidopa	Expired	✓	✓		✓				Antiparkinsonian
Carbimazole	Expired	✓	✓		✓				Antihyperthyroidism
Chlorthalidone	Expired	✓	✓		✓			✓	Antihypertensive
Dapoxetine Hydrochloride	Decentralised	✓	✓					✓	Premature Ejaculation
Deutetrabenazine	Not Approved	✓	✓						CNS Agent
Dexmedetomidine	Expired	✓							Sedative

★ - Under Development

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Divalproex Sodium	Not approved	✓	✓			✓		✓	Anticonvulsant
Docosanol	Expired	✓	✓			✓	✓		Antiviral
Doxycycline Hyclate	Expired	✓							Antibiotic
Doxycycline Monohydrate	Expired	✓							Antibiotic
Efinaconazole	Not approved	✓	✓			✓		✓	Antifungal
Folic Acid	Expired	✓							Vitamin
Foscarnet Sodium	Expired	✓	✓		✓				Antiviral
Gabapentin Enacarbil	Not approved	✓							Anticonvulsant
Gemifloxacin Mesylate	Not approved	✓							Antibacterial
Ibuprofen	Expired	★							Anti-inflammatory
Ilaprazole	Not Approved	★							Anti-ulcerative
Indacaterol	Expired	★							Chronic obstructive pulmonary disease
Ipragliflozin L-Proline	Not approved	✓							Antidiabetic
Ketamine	Expired	✓			✓				Anaesthetic
Lercanidipine Hydrochloride	Decentralised	✓	✓	✓					Antihypertensive
Levodopa	Expired	✓	✓		✓				Antiparkinsonian
Lomitapide Mesylate	Expired	✓	✓						Antihyper Lipoproteinemic
Luliconazole	Not approved	✓	✓				✓		Antifungal
Lumacaftor	19-Nov-23	✓	✓						Cystic Fibrosis
Mesalamine /Mesalazine	Expired	✓	✓		✓				Gastrointestinal Agent
Methimazole	Decentralised	✓	✓		✓				Antithyroid
Mirtazapine (Anhydrous)	Expired	✓			✓				Antidepressant
Mirtazapine (Hemihydrate)	Expired	✓	✓		✓		✓		Antidepressant
Netarsudil Mesylate	19-Nov-27	✓	✓						Antiglaucomas
Nitrofurantoin Anhydrous	Expired	✓	✓		✓	✓			Antibiotic
Nitrofurantoin Anhydrous (Macrocrystal)	Not applicable	✓	✓		✓	✓			Antibiotic
Nitrofurantoin Hydrous	Not applicable	✓	✓			✓			Antibiotic
Pemafibrate	Not approved	★							Hyperlipidaemia
Ospemifene	15-Jan-23	✓							Dyspareunia
Ozenoxacin	Not approved	✓	✓						Antibacterials
Penciclovir	Decentralised	✓	✓				✓		Antiviral
Raltegravir Potassium	Expired	✓							Antiretroviral
Rotigotine	Expired	★							AntiParkinson's disease (PD)
Sapropterin Dihydrochloride	Expired	✓							Phe-hydroxylate Activator
Selexipag	12-May-24	✓	✓	✓		✓		✓	Antihypertensives
Strontium Ranelate	Expired	✓							Osteoporosis

★ - Under Development

## APIs with NCE EXPIRED

PRODUCT	EU Filing Date (DE-2)	Tech pack	DMF					Therapeutic Category
			US	EU	CEP	CA	CH	
Tazarotene	Expired	★						Acne vulgaris
Tigecycline	Expired	✓	✓	✓			✓	Antibiotic
Varenicline Tartrate	Expired	✓	✓	✓			✓	Smoking Cessation Agent
Zonisamide	Expired	✓	✓					Anticonvulsant

## Inorganic APIs

PRODUCT	API Expired	Tech pack	DMF					Therapeutic Category
			US	EU	CEP	CA	CH	
Calcium Gluconate	Expired							Acute symptomatic hypocalcemia
Chromic Chloride	Expired	✓						Supplement in nutritional
Cupric Sulfate	Expired	✓						Supplement in nutritional
Manganese Sulfate	Expired							Supplement in nutritional
Pottassium Phosphate	Expired							Prevent hypophosphatemia (low blood levels of phosphorus).
Selenious Acid	30-Apr-19	✓						Supplement in nutritional
Sodium Phosphate	Expired	✓						Colonoscopy, Diagnostic aid
Zinc Sulfate	Expired							Supplement in nutritional

## Intermediates

Voriconazole CSA salt: (2R,3S)-2-(2,4-Difluorophenyl)-3-(5-fluoropyrimidin-4-yl)-1-(1H-1,2,4-triazol-1-yl) butan-2-ol R-(-)-10-camphor sulphionate	CAS : 137234 - 71 -0
Varenicline Tartrate: 1-(7,8-dinitro-4,5-dihydro-1H-1,5-methanobenzo[d]azepin-3(2H)-yl)-2,2,2-trifluoroethanone	CAS 230615-59-5

★ - Under Development

**Note: Above products will NOT be supplied to countries in which these could be in conflict with existing patents.  
The final responsibility lies exclusively with the buyer.**