

API PRODUCT PORTFOLIO

PRODUCT	INDICATION	API MICRONIZED	CEP/DMF
Arformoterol tartrate^P polymorph A and D	COPD		US-CN DMF
Formoterol fumarate	Asthma and COPD	√	CEP / US-JP-KR-CN DMF
Glycopyrronium bromide^P	COPD	√	CEP / US-CN DMF
Indacaterol maleate^P	Asthma and COPD	√	EU/US DMF
Salmeterol xinafoate^P	Asthma and COPD	√	CEP / US-CN-KR DMF
Tiotropium Bromide	COPD	√	CEP / US-CN DMF

API PRODUCT PIPELINE

PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Abediterol	Asthma and COPD			2023	2023
Aclidinium bromide	COPD	√	√	Q3 2020	Q1 2021
Batefenterol	COPD			2023	2024
Olodaterol^P	COPD	√	√	Q3 2020	Q1 2022
Revefenacin	COPD			Q2 2021	Q4 2021
Umeclidinium bromide	COPD	√	√	Q4 2020	Q3 2021
Vilanterol	Asthma and COPD	√	√	√	Q3 2020

CEP = Products with Certificate of Suitability / P = Patent applications/granted patents owned by Neuraxpharm

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THERAPEUTIC AREA	PRODUCT	INDICATION	API MICRONIZED	CEP/DMF
Antiallergics	Loratadine ^P	Allergy	√	JP DMF
Antiarrhythmics	Dronedarone ^P	Atrial fibrillation & general arrhythmia		DMF
Antiasthmatics, COPD and respiratory diseases	Arformoterol tartrate ^P polymorph A and D	COPD		US-CN DMF
	Formoterol fumarate	Asthma and COPD	√	CEP/US-JP-KR-CN DMF
	Glycopyrronium bromide ^P	COPD	√	CEP/ US-CN DMF
	Indacaterol maleate ^P	Asthma and COPD	√	EU/US DMF
	Montelukast sodium ^P	Asthma, allergic & seasonal rhinitis		EU-JP DMF
	Salmeterol xinafoate ^P	Asthma and COPD	√	CEP/ US-CN-KR DMF
	Tiotropium Bromide	COPD	√	CEP/US-CN DMF
Antiemetics	Granisetron base ^P	Emesis		US DMF
	Granisetron hydrochloride ^P	Emesis		CEP/ US-JP-KR DMF
	Ondansetron base ^P	Emesis	√	EU-US DMF
	Ondansetron hydrochloride ^P	Emesis	√	CEP/US DMF
Antifungals	Fluconazole ^P	Antifungal		CEP/US-KR DMF
Antihypertensive	Carvedilol ^P	Hypertension, angina, heart failure		JP DMF
	Enalapril maleate ^P	Hypertension		CEP/KR DMF
	Imidapril	Hypertension		EU DMF
	Nitrendipine	Hypertension	√	CEP/DMF
Antimigrainics	Eletriptan HBr ^P	Migraine	√	JP DMF
	Rizatriptan benzoate ^P	Migraine	√	EU-US DMF
	Zolmitriptan ^P	Migraine	√	EU-US DMF
Antipsychotics	Asenapine maleate ^P	Schizophrenia and acute mania	√	
	Olanzapine ^P	Schizophrenia, psychosis		EU-US- DMF
	Quetiapine hemifumarate ^P	Schizophrenia, psychosis		JP-KR DMF
	Risperidone ^P	Schizophrenia, psychosis	√	CEP/US-KR DMF
Antithrombotics	Prasugrel base ^P	Prophylaxis and therapy of thrombosis		EU DMF
	Rivaroxaban	Thrombosis. Stroke		DMF
Spasmolytic	Otilonium bromide	Irritable bowel syndrome		EU DMF

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THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Antiasthmatics, COPD and respiratory diseases	Abediterol	Asthma and COPD			2023	2023
	Aclidinium bromide	COPD	√	√	Q3 2020	Q1 2021
	Batefenterol	COPD			2023	2024
	Olodaterol^P	COPD	√	√	Q3 2020	Q1 2022
	Revefenacin	COPD			Q2 2021	Q4 2021
	Umeclidinium bromide	COPD	√	√	Q4 2020	Q3 2021
	Vilanterol	Asthma and COPD	√	√	√	Q3 2020
Antiemetics	Aprepitant	Emesis	√	√	√	Q4 2020
Antihypertensive	Clevidipine^P	Hypertension	√	√	Q3 2020	Q2 2021
Antiparkinson	Benserazide	Parkinson's disease			Q4 2020	Q2 2021
	Tetrabenazine	Huntington's disease chorea and Tardive dyskinesia	√	√	√	Q3 2020
Antipsychotics	Olanzapine pamoate	Schizophrenia, psychosis	√	√	√	Q1 2021
	Paliperidone Palmitate	Schizophrenia, bipolar mania				
	Pipamperone	Schizophrenia	√	√	Q3 2020	Q1 2021
Antithrombotics	Apixaban^P	Venous thromboembolism	√	√	√	√
Other disorders	Tafamidis	Transthyretin amyloidosis	√	Q3/Q4 2020	Q4 2020	Q3 2021
	Tolvaptan	Hyponatremia	√	√	Q4 2020	Q1 2022
Urologics	Imidafenacin^P	Urinary incontinence	√	√		

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