

THERAPEUTIC AREA	PRODUCT	INDICATION	API MICRONIZED	CEP/DMF
Antiallergics	<b>Desloratadine</b>	Allergy	√	EU-CN DMF
	<b>Loratadine<sup>P</sup></b>	Allergy		JP DMF
Antiarrhythmics	<b>Dronedaron<sup>P</sup></b>	Atrial fibrillation & general arrhythmia		DMF
Antiasthmatics, COPD and respiratory diseases	<b>Arformoterol tartrate<sup>P</sup> polymorph A and D</b>	COPD		US-CN DMF
	<b>Formoterol fumarate</b>	Asthma and COPD	√	CEP/US-JP-KR-CN DMF
	<b>Glycopyrronium bromide<sup>P</sup></b>	COPD	√	CEP/ US DMF
	<b>Montelukast sodium<sup>P</sup></b>	Asthma, allergic & seasonal rhinitis		EU-JP DMF
	<b>Salbutamol sulfate</b>	Asthma and COPD	√	
	<b>Salmeterol xinafoate<sup>P</sup></b>	Asthma and COPD	√	CEP/ US-CN DMF
Antiemetics	<b>Granisetron base<sup>P</sup></b>	Emesis		US DMF
	<b>Granisetron hydrochloride<sup>P</sup></b>	Emesis		CEP/ US-JP-KR DMF
	<b>Ondansetron base<sup>P</sup></b>	Emesis		EU-US DMF
	<b>Ondansetron hydrochloride<sup>P</sup></b>	Emesis		CEP/US DMF
Antifungals	<b>Fluconazol<sup>P</sup></b>	Antifungal		CEP/US-KR DMF
Antihypertensive	<b>Carvedilol<sup>P</sup></b>	Hypertension, angina, heart failure		JP DMF
	<b>Enalapril maleate<sup>P</sup></b>	Hypertension		CEP/KR DMF
	<b>Imidapril</b>	Hypertension		EU DMF
	<b>Nitrendipine</b>	Hypertension		CEP/DMF
	<b>Telmisartan<sup>P</sup></b>	Hypertension		JP DMF
Antimigrainics	<b>Eletriptan HBr<sup>P</sup></b>	Migraine	√	JP DMF
	<b>Rizatriptan benzoate<sup>P</sup></b>	Migraine	√	EU-US DMF
	<b>Zolmitriptan<sup>P</sup></b>	Migraine	√	EU-US DMF
Antipsychotics	<b>Asenapine<sup>P</sup></b>	Schizophrenia and acute mania	√	
	<b>Clomethiazole</b>	Insomnia		EU DMF
	<b>Olanzapine<sup>P</sup></b>	Schizophrenia, psychosis		EU-US- DMF
	<b>Quetiapine hemifumarate<sup>P</sup></b>	Schizophrenia, psychosis		JP-KR DMF
Anti-thrombotics	<b>Risperidone<sup>P</sup></b>	Schizophrenia, psychosis	√	CEP/US-KR DMF
	<b>Prasugrel base<sup>P</sup></b>	Prophylaxis and therapy of thrombosis		EU DMF

CEP = Products with Certificate of Suitability

P = Patent applications/granted patents owned by NuPharm Group

Products protected by valid patents are developed with no commercial purposes. These products are under development for uses related to the activities stated in the Hatch-Waxman Act [35 U.S.C. § 271(e)(1)]. These products are solely for uses related to the development and submission of information to obtain a marketing authorization. None of the products are offered for sale or supplied to countries in which they could be in conflict with valid patents.

THERAPEUTIC AREA	PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Antiasthmatics, COPD and respiratory diseases	<b>Abediterol</b>	Asthma and COPD			Early R&D	
	<b>Acclidinium bromide</b>	COPD		Q4 2018	Q1 2019	
	<b>Batefenterol</b>	COPD			Early R&D	
	<b>Indacaterol maleate<sup>P</sup></b>	Asthma and COPD	√	√	√	2019
	<b>Olodaterol<sup>P</sup></b>	COPD	Q1 2019	Q4 2018	Q1 2019	
	<b>Revefenacin</b>	COPD			Early R&D	
	<b>Roflumilast</b>	COPD with chronic bronchitis		Q1 2019		
	<b>Tiotropium Bromide</b>	COPD	√	√	√	2019
	<b>Umeclidinium bromide</b>	COPD	√	√	Q4 2018	2019
	<b>Vilanterol</b>	Asthma and COPD	Q4 2018	Q4 2018	Q4 2018	2019
Antiemetics	<b>Aprepitant</b>	Emesis	√	√	√	2019
Antihypertensive	<b>Clevidipine<sup>P</sup></b>	Hypertension		√		
Antihyperparathyroidism	<b>Cinacalcet</b>	Hyperparathyroidism / Hypercalcaemia	√	√	√	
Antiparkinson	<b>Tetrabenazine</b>	Parkinson disease	√	√	Ongoing	2019
	<b>(+) Tetrabenazine</b>	Parkinson disease	√	√		
Antipsychotics	<b>Brexiprazole</b>	Schizophrenia and major depressive disorders		Q4 2018	Q1 2019	
	<b>Olanzapine pamoate (sterile)</b>	Schizophrenia, psychosis	√	√		2019
Anti-thrombotics	<b>Apixaban<sup>P</sup></b>	Venous thromboembolism	√	√	√	
	<b>Prasugrel hydrochloride</b>	Prophylaxis and therapy of thrombosis	√	√		
	<b>Rivaroxaban<sup>P</sup></b>	Thrombosis. Stroke	√	√	√	
Other disorders	<b>Tolvaptan</b>	Hiponatremia	√	√		
Urologics	<b>Imidafenacin<sup>P</sup></b>	Urinary incontinence	√	√		

CEP = Products with Certificate of Suitability

P = Patent applications/granted patents owned by NuPharm Group

Products protected by valid patents are developed with no commercial purposes. These products are under development for uses related to the activities stated in the Hatch-Waxman Act [35 U.S.C. § 271(e)(1)]. These products are solely for uses related to the development and submission of information to obtain a marketing authorization. None of the products are offered for sale or supplied to countries in which they could be in conflict with valid patents.