

API	Indication	R&D Validation batches	DMF
<b>RESPIRATORY</b>			
Abediterol	Asthma and COPD	early R&D	
Acridinium bromide	COPD	R&D	
Albuterol sulfate	Asthma and COPD	√	2018
Arformoterol tartrate <sup>P</sup> polymorph A and D	COPD	√	√
Batefenterol	COPD	early R&D	
Formoterol fumarate	Asthma and COPD	√	√ <sup>CoS</sup>
Glycopyrronium bromide <sup>P</sup>	COPD	√	√
Indacaterol maleate <sup>P</sup>	Asthma and COPD	√	2019
Olodaterol <sup>P</sup>	COPD	Q2 2018	
Revefenacin	COPD	R&D	
Salbutamol sulfate	Asthma and COPD	√	2018
Salmeterol xinafoate <sup>P</sup>	Asthma and COPD	√	√ <sup>CoS</sup>
Tiotropium Bromide (monohydrate/anhydrate/ amorphous)	COPD	√	
Umeclidinium bromide	COPD	√	
Vilanterol trifenate	Asthma and COPD	Q2 2018	
<b>GENERIC</b>			
Apixaban <sup>P</sup>	Venous thromboembolism	√	2019
Aprepitant	Emesis	√	2019
Asenapine <sup>P</sup>	Schizophrenia and acute mania	√	√
Brexipiprazole	Schizophrenia and major depressive disorder	2018	
Brivaracetam	Antiepileptic	early R&D	
Carvedilol <sup>P</sup>	Hypertension, angina, heart failure	√	√
Cinacalcet	Hyperparathyroidism / Hypercalcaemia	√	2018
Clevidipine <sup>P</sup>	Hypertension	lab. samples	
Clomethiazole	Insomnia	√	√
Crisaborole <sup>P</sup>	Atopic dermatitis and psoriasis	√	2019
Desloratadine	Allergy	√	√

CoS = Products with Certificate of Suitability

P = Patent applications/granted patents owned by NuPharm Group



Listed products protected by valid patents are developed solely for purposes related to the development, preparation and submission of information to obtain a Marketing Authorisation. In particular these products are under development for uses related to the activities stated in Art. 10.6 of Directive 2001/83/EC, i.e. activities carried out to obtain a Marketing Authorisation. None of the products are offered for sale or supplied to countries in which they could be in conflict with valid patents.

API	Indication	R&D Validation batches	DMF
<b>GENERICS</b>			
Dronedarone <sup>P</sup>	Atrial fibrillation & general arrhythmia	√	√
Eletriptan HBr <sup>P</sup>	Migraine	√	√
Enalapril maleate <sup>P</sup>	Hypertension	√	√ <sup>CoS</sup>
Fluconazol <sup>P</sup>	Antifungal	√	√ <sup>CoS</sup>
Granisetron base <sup>P</sup>	Emesis	√	√
Granisetron HCl <sup>P</sup>	Emesis	√	√ <sup>CoS</sup>
Iloperidone	Schizophrenia and other psychotic disorders	√	
Imidafenacin <sup>P</sup>	Urinary incontinence	√	2018
Imidapril	Hypertension	√	√
Loratadine <sup>P</sup>	Allergy	√	√
Luliconazole <sup>P</sup>	Antifungal	√	2019
Montelukast sodium <sup>P</sup>	Asthma, allergic & seasonal rhinitis	√	√
Nitrendipine	Hypertension	√	√ <sup>CoS</sup>
Olanzapine <sup>P</sup>	Schizophrenia, psychosis	√	√
Olanzapine pamoate (sterile)	Schizophrenia, psychosis	√	2019
Olmesartan medoxomil	Hypertension	√	
Ondansetron base <sup>P</sup>	Emesis	√	√
Ondansetron hydrochloride <sup>P</sup>	Emesis	√	√ <sup>CoS</sup>
Prasugrel base <sup>P</sup>	Prophylaxis and therapy of thrombosis	√	√
Prasugrel hydrochloride	Prophylaxis and therapy of thrombosis	√	
Quetiapine hemifumarate <sup>P</sup>	Schizophrenia, psychosis	√	√
Risperidone <sup>P</sup>	Schizophrenia, psychosis	√	√ <sup>CoS</sup>
Rivaroxaban <sup>P</sup>	Thrombosis. Stroke	√	2018
Rizatriptan benzoate <sup>P</sup>	Migraine	√	√
Roflumilast	COPD with chronic bronchitis	√	
Sarizotan	Rett syndrome	Q4 2018	
Telmisartan <sup>P</sup>	Hypertension	√	√
Tetrabenazine	Parkinson disease	√	
(+) Tetrabenazine	Parkinson disease	√	
Tolvaptan	Hiponatremia	√	2018
Zolmitriptan <sup>P</sup>	Migraine	√	√

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