INHALATION APIs

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	\checkmark	CEP/US-JP-KR-CN-RU DMF	
Glycopyrronium bromide ^P	COPD	\checkmark	CEP/US-CN-KR-RU DMF	
Indacaterol maleate ^p	Asthma and COPD	\checkmark	EU/US-KR-RU DMF	
Salmeterol xinafoate ^P	Asthma and COPD		CEP/US-CN-KR DMF	
Tiotropium bromide monohydrate	COPD	\checkmark	CEP/US-CN DMF	
Vilanterol trifenatate	Asthma and COPD	\checkmark	EU/US DMF	

API PRODUCT PIPELINE

PRODUCT	INDICATION	SAMPLES	TECHNICAL PACKAGE	VALIDATION BATCH	DMF
Aclidinium bromide	COPD		\checkmark	\checkmark	Q4 2021
Indacaterol acetate	Asthma	Q4 2021	Q2 2022	Q3 2022	Q2 2023
Olodaterol [®]	COPD	\checkmark	\checkmark	\checkmark	Q1 2023
Revefenacin	COPD	\checkmark	\checkmark	Q4 2021	Q3 2022
Umeclidinium bromide	COPD		\checkmark	Q4 2021	Q3 2022

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

Listed products protected by valid patents are developed solely for purposes related to the development, preparation and submission of information to obtain a Marketing Authorization. In particular these products are under development for uses related to the activities stated in Art. 10.6 of Directive 2001/83/EC amended by the Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, i.e. activities carried out 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.