

Certificate of Analysis

Product name: Glycopyrronii bromidum

Batch number / Weight: 22B10-B05-226334 / 1 G

Analysed according to: Ph.Eur.10.8

Number of analysis / Inspection Code 22B10-B05 / INS-22-4753

Reference Code / No.: V01504 / 21015380

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
Acidity or alkalinity	NaOH ≤0,2 ml / Red or orange	Conform		
Impurity N	≤0,2	<0,05	%	
Related substances	Conform	Conform	%	
Impurity I	≤0,3	<0,05	%	
Impurity E	≤0,2	<0,05	%	
Unspecified impurities	≤0,10	<0,05	%	
Total impurities	≤0,5	<0,05	%	
Loss on drying	≤0,5	0,02	%	
Sulphated ash	≤0,1	0,05	%	
Residual solvents	CPMP/ICH/260/06	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Glycopyrronium bromide	99,0 - 101,0	100,2	%m/m	
Total aerobic microbial count (TA)	≤200	<10	CFU / g	
Total yeasts and moulds (TYMC)	≤20	<10	CFU/g	
E. coli	Absent	Conform	/ g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Isopropanol	≤ 3000	238	ppm	
Heptane	≤ 1000	<20	ppm	
Methanol	≤ 1000	<25	ppm	

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab EL Spol

Release:

Agnieszka Pszczółka

Qualified Person

12-12-2022

Expiration: 20-11-2026

Conclusion: APPROVED

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