

Certificate of Analysis

Product name: Glycopyrronii bromidum

Batch number / Weight: 21H13-B22-215581 / 1 G

Analysed according to: Ph. Eur.

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 \leq 0,2 ml / Red or orange	Conform		
Impurity N	\leq 0,2	< 0,05	%	
Related substances	Conform	Conform	%	
Impurity I	\leq 0,3	< 0,05	%	
Impurity E	\leq 0,2	< 0,05	%	
Unspecified impurities	\leq 0,10	< 0,05	%	
Total impurities	\leq 0,5	< 0,05	%	
Loss on drying	\leq 0,5	0,04	%	
Sulphated ash	\leq 0,1	0,04	%	
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	99,4	%m/m	
Total aerobic microbial count (TA)	\leq 200	Conform	CFU / g	
Total yeasts and moulds (TYMC)	\leq 20	Conform	CFU/g	
E. coli	Absent	Conform	/ g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

15-12-2021

Expiration: 24-05-2026

Conclusion: APPROVED

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