

## Certificate of Analysis

**Product name:** Glycopyrronii bromidum  
**Batch number / Weight:** 20B03-F12-219974 / 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 ≤0,2 ml / Red or orange	Conform		
Impurity N	≤0,2	0,0	%	
Related substances	Conform	Conform	%	
Impurity I	≤0,3	0,0	%	
Impurity E	≤0,2	<0,05	%	
Unspecified impurities	≤0,10	<0,05	%	
Total impurities	≤0,5	0,0	%	
Loss on drying	≤0,5	0,1	%	
Sulphated ash	≤0,1	0,0	%	
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	100,5	%m/m	
Total aerobic microbial count (TA)	≤200	Conform	CFU / g	
Total yeasts and moulds (TYMC)	≤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:  
Agnieszka Pszczółka  
Qualified Person

22-04-2022

Expiration: 30-09-2024

Conclusion: APPROVED

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