

Certificate of Analysis

Productname: Glycopyrronii bromidum
Number of analysis/Inspection Code: 3 / KEUR-181018B
Batchnumber: 20B03-F12-368265
Reference code / No.: 2382 / 19013345
Analysed according to: PHEUR10.0+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Bromide
Appearance of solution	Clear and colourless	Conform		2% <i>m/V</i>
Acidity or alkalinity	NaOH $\leq 0,2$ ml / Red or orange	Conform		
Impurity N	$\leq 0,2$	0,0	%	HPLC
Related substances	Conform	Conform	%	HPLC
Impurity I	$\leq 0,3$	0,0	%	
Impurity E	$\leq 0,2$	$\leq 0,05$	%	
Unspecified impurities	$\leq 0,10$	$\leq 0,05$	%	
Total impurities	$\leq 0,5$	0,0	%	
Loss on drying	$\leq 0,5$	0,1	%	3h 105 °C
Sulphated ash	$\leq 0,1$	0,0	%	
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Assay Glycopyrronium bromide	99,0 - 101,0	100,5	% <i>m/m</i>	Dried
Total aerobic microbial count (TAMC)	≤ 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 laboratory Pharma Cosmetic + microbiel.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

03/10/20

Expiration: 09-2024

Conclusion: APPROVED

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