

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%/V
Acidity or alkalinity	NaOH <=0,2 ml / Red or orange	Conform		
Impurity N	<=0,2	0,0	%	HPLC
Related substances	Conform	Conform	%	HPLC
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	%	3h 105 °C
Sulphated ash	<=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	%m/m	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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