



## Certificate of Analysis

Productname: **Glycopyrronii bromidum**  
Number of analysis/Inspection Code: 1 / KEUR-104188B  
Batchnumber: **14A14-B06-290005** ✓  
Reference code / No.: 2382 / 77146A005  
Analysed according to: **PH.EUR 8.0**



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% <sub>m/V</sub>
Acidity or alkalinity	Red or orange	Conform		
Impurity N	<=0,2	<0,1	%	HPLC
Related substances	Conform	Conform	%	HPLC
Impurity I	<=0,3	n.d.	%	
Impurity E	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Loss on drying	<=0,5	<0,1	%	3 h 105 °C; data producer
Sulphated ash	<=0,1	Conform	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Glycopyrronium bromide	99,0 - 101,0	99,1	% <sub>m/m</sub>	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

Analyse performed by the authorized lab Proxylabs+Microb..

Release:  
Drs. M.V. Garcia Alia  
Pharmacist - QA Manager / QP

02/03/14

Expiration: 10-2018 ✓

Conclusion: APPROVED

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