

Certificate of Analysis

Product name: Ipratropii bromidum
Batch number / Weight: 23C07-B08-013964 / 1 g
Producer / Producer Batch Number: Olon SpA Lodigiano (ex Sifavitor Srl) / 2350000434
Analyzed according to: Ph. Eur.11.8
Number of Analysis / Certificate no.: 23C07-B08 / QO0020320

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification	A, E	Conform		
Appearance of solution	Clear / <=GY7	Conform		
pH	5,0 - 7,5	6,20		
Impurity A	<=0,1	<0,1	%	
Related substances	Conform	Conform		
Impurity D	<=0,05	<0,03	%	
Impurity B	<=0,1	<0,03	%	
Impurity C	<=0,1	<0,03	%	
Unspecified impurities	<=0,10	<0,03	%	
Total impurities	<=0,25	0,000	%	
Water (Karl Fischer)	3,9 - 4,4	4,31	%	
Sulfated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 100,5	100,00	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
Correction factor		1,001		

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Own lab

Release:

18-8-2025
 Dominika Sołtysik
 Qualified Person

Expiration: 12-2-2028

Conclusion: APPROVED

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