

Certificate of Analysis

Product name: Oxybutynini hydrochloridum
Batch number / Weight: 21H27-B01-216404 / 1 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear / \leq BY5	Conform		
Optical rotation	-0,10 - +0,10	-0,007	°	
Related substances	Conform	Conform		
Impurity A	\leq 1,5	0,00	%	
Impurity C		$<$ 0,05	%	
Impurity D		0,059	%	
Impurity F		0,00	%	
Unspecified impurities	\leq 0,10	$<$ 0,05	%	
Sum of impurities other than A	\leq 0,5	0,06	%	
Loss on drying	\leq 3,0	1,87	%	
Sulphated ash	\leq 0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Oxybutynine hydrochlorid	99,0 - 102,0	100,28	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

16-03-2022

Expiration: 30-06-2026

Conclusion: APPROVED

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