Certificate of Analysis

Product name: **Oxybutynini hydrochloridum**

Batch number / Weight: **21H27-B01-222438 / 1 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **21H27-B01 / INS-22-0792**

Reference Code / No.: **V01678 / CA0100187**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	Clear / <=BY5	Conform		
Optical rotation	-0,10 - +0,10	-0,007	°	
Related substances	Conform	Conform		
Impurity A	<=1,5	0,00	%	
Impurity C	<=0,15	<0,05	%	
Impurity D	<=0,15	0,059	%	
Impurity F	<=0,15	0,00	%	
Unspecified impurities	<=0,10	<0,05	%	
Sum of impurities other than A	<=0,5	0,06	%	
Loss on drying	<=3,0	1,87	%	
Sulphated ash	<= 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		

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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 FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

29-08-2022

Expiration: 30-06-2026

Conclusion: APPROVED

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