

## Certificate of Analysis

**Productname:** Oxybutynini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-188052B  
**Batchnumber:** 20K10-F04-375781  
**Reference code / No.:** 4098 / OH/044/2020-2021  
**Analysed according to:** PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
Appearance of solution	Clear / <=BY5	Conform		10%m/V
Optical rotation	-0,10 - +0,10	-0,01	°	10%m/V
Related substances	Conform	Conform		HPLC
Impurity A	<=1,5	n.d.	%	
Unspecified impurities	<=0,10	0,06	%	
Sum of impurities other than A	<=0,5	0,1	%	
Loss on drying	<=3,0	2,2	%	105°C
Sulphated ash	<= 0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Oxybutynine hydrochloride	99,0 - 102,0	100,3	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
Paul Hofman  
Pharmacist - Qualified Person

01/05/21

Expiration: 09-2025

Conclusion: APPROVED

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