

Certificate of Analysis

Product name: **Propanthelini bromidum**

Batch number / Weight: **22G18-B02-221869 / 1 G**

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

Number of analysis / Inspection Code **22G18-B02 / INS-22-6692**

Reference Code / No.: **V01850 / PBR1002109**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white powder slightly hygroscopic	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Appearance of solution	Clear	Conform		
Related substances	Conform	Conform		
Any impurity	$\leq 1,0$	0,09	%	
At most one peak $\geq 0,5\%$	≤ 1	0		
Loss on drying	$\leq 1,0$	0,16	%	
Sulphated ash	$\leq 0,1$	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Propantheline bromide	98,5 - 101,0	99,97	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Benzene		0,0	ppm	
Chloroform		<60	ppm	
Toluene		<890	ppm	
Methylethylketone	≤ 5000	<5000	ppm	

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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 Own lab

Release:
Dominika Soltysik
Qualified Person

23-09-2022

Expiration: 31-08-2025

Conclusion: APPROVED

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