

Certificate of Analysis

Productname: Propanthelini bromidum
Number of analysis/Inspection Code: 1 / KEUR-185861B
Batchnumber: 20G10-F05-373522
Reference code / No.: 2123 / PBR1001913
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white powder	Conform		
Appearance	zwak hygroscopisch	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		Bromide
Appearance of solution	Clear	Conform		0.6 g / 20 ml (MeOH)
Related substances	Conform	Conform		HPLC
Any impurity	<=1,0	0,5	%	
No more than one peak >=0,5%	<=1	Conform		
Loss on drying	<=1,0	0,1	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Propantheline bromide	98,5 - 101,0	100,4	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

09/23/20

Expiration: 11-2023

Conclusion: APPROVED

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