

Certificate of Analysis

Productname: Hyoscini butylbromidum
Number of analysis/Inspection Code: 1 / KEUR-180717B
Batchnumber: 20A29-F07-367903
Reference code / No.: 1272 / 31819004
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	-18 - -20	Conform		Specific optical rotation
Identification C	Conform	Conform		IR-spectrum
Identification F	Yellow-white	Conform		Bromide
Appearance of solution	Clear / colourless	Conform		5%m/V
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	-18 - -20	-19		5%m/V
Related substances	Conform	Conform		HPLC
Impurity A	<=0,15	<0,05	%	
Any other impurity	<=0,10	0,06	%	
Total impurities	<=0,4	0,1	%	
Loss on drying	<=2,5	0,1	%	105 °C
Sulphated ash	<=0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Hyoscine Butylbromide	98,0 - 101,0	99,7	%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:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/25/20

Expiration: 02-2024

Conclusion: APPROVED

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