

Certificate of Analysis

Productname: Mebeverini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-185023B
Batchnumber: 19K22-F01-370857
Reference code / No.: 2883 / 411
Analysed according to: BP2020

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	White	Conform		Chloride
pH	4,5 - 6,5	5,5		2%m/V
Related substances	Conform	Conform		HPLC
Impurity J	<=0,2	0,0	%	
Unspecified impurities	<=0,10	0,06	%	
Total impurities	<=0,3	0,1	%	
Loss on drying	<=0,5	0,1	%	1 h 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 Mebeverine hydrochloride	99,0 - 101,0	99,8	%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

08/17/20

Expiration: 06-2024

Conclusion: APPROVED

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