

Certificate of Analysis

Product name: **Mebeverini hydrochloridum**
Batch number / Weight: **19K22-F01-217198 / 25 G**
Analysed according to: **British Pharmacopoeia**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	White	Conform		
pH	4,5 - 6,5	5,5		
Related substances	Conform	Conform		
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	%	
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	99,8	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

14-01-2022

Expiration: 30-06-2024

Conclusion: APPROVED

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