

## Certificate of Analysis

**Product name:** **Mebeverini hydrochloridum**  
**Batch number / Weight:** **21B05-B18-216720 / 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	5,46		
Related substances	Conform	Conform		
Impurity J	$\leq 0,2$	0,00	%	
Unspecified impurities	$\leq 0,10$	0,06	%	
Total impurities	$\leq 0,3$	0,06	%	
Loss on drying	$\leq 0,5$	0,02	%	
Sulphated ash	$\leq 0,1$	0,01	%	
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:  
 Agnieszka Pszczółka  
 Qualified Person

02-03-2022

Expiration: 30-06-2024

Conclusion: APPROVED

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