

Certificate of Analysis

Productname: Mephenesinum
Number of analysis/Inspection Code: 1 / KEUR-180637B
Batchnumber: 19J25-F08-366420
Reference code / No.: 4471 / B/MN/07/19/057
Analysed according to: INTERN

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or crystalline needles	Conform Conform		
Identification A	70 - 73	71	°C	Melting point
Identification B	Conform	Conform		
Identification C	Conform	Conform		Colour reaction
pH	5,0 - 7,0	6,0		
Appearance of solution	Clear, colorless or slightly yellowish	Conform		
Related substances	Conform	Conform		HPLC
Imp.3-phenoxy 1,2propanediol	<=0,5	<0,1	%	
O-cresol	<=50	n.d.	ppm	
Tot imp 3 phenoxy 1,2 propaned	<=0,5	0,1	%	
Loss on drying	<=0,5	<0,1	%	
Sulphated ash	<=0,1	<0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Mephenesine	99,0 - 101,0	99,5	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Proxylabs.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/21/20

Expiration: 06-2024

Conclusion: APPROVED

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