

Certificate of Analysis

Productname: Trometamolum
Number of analysis/Inspection Code: 1 / KEUR-179488B
Batchnumber: 18H13-B04-363963
Reference code / No.: 4282 / E300003986
Analysed according to: PH.EUR 9.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform Conform		
Identification B	168 - 174	171	°C	Melting point
Identification C	Conform	Conform		IR-spectrum
Appearance of solution	Clear and colourless	Conform		5%m/V
pH	10,0 - 11,5	10,9		5%m/V
Related substances	<=1,0	Conform	%	TLC
Chlorides	<= 100	Conform	ppm	
Iron	<= 10	Conform	ppm	
Loss on drying	<= 0,5	0,3	%	105°C, 5h
Sulphated ash	<= 0,1	0,0	%	
Endotoxins	<= 0,03	Conform	IU / mg	LAL-test
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Trometamolum	99,0 - 100,5	100,0	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Remark	Use only as excipient!	.		

Analysis performed by the authorized laboratory Eurofins.

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

01/09/20

Expiration: 03-2023

Conclusion: APPROVED

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