

Certificate of Analysis

Product name: **Trometamolum**

Batch number / Weight: **21I30-B05-224116 / 100 G**

Analysed according to: **Ph.Eur.10**

Number of analysis / Inspection Code **21I30-B05 / INS-22-0147**

Reference Code / No.: **V01665 / E300028159**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
	or colourless crystals			
Identification B	168 - 174	172,1	°C	
Identification C	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	10,0 - 11,5	10,95		
Related substances	<=1,0	Conform	%	
Chlorides	<= 100	Conform	ppm	
Iron	<= 10	Conform	ppm	
Loss on drying	<= 0,5	0,41	%	
Sulphated ash	<= 0,1	0,005	%	
Endotoxins	<= 0,03	Conform	IU / mg	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Trometamolum	99,0 - 100,5	99,23	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Correction factor		1,012		

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:

Agnieszka Pszczółka

Qualified Person

13-09-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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