

Certificate of Analysis

Product name: **Trometamol**
Batch number / Weight: **21I30-B05-213923 / 100 G**
Analysed according to: **Ph. Eur.**

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 Trometamol	99,0 - 100,5	99,23	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Remark	Use only as excipient!			

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

04-02-2022

Expiration: 31-05-2026

Conclusion: APPROVED

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