

Certificate of Analysis

Product name: **Trometamol**

Batch number / Weight: **22B07-B18-217781 / 100 G**

Analysed according to: **Ph. Eur. 10.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or colourless crystals	Conform		
	or colourless crystals			
Identification B	168 - 174	172	°C	
Identification C	Conform	Conform		
Appearance of solution	Clear and colourless	Conform		
pH	10,0 - 11,5	11,1		
Related substances	<=1,0	Conform	%	
Chlorides	<= 100	Conform	ppm	
Iron	<= 10	Conform	ppm	
Loss on drying	<= 0,5	0,3	%	
Sulphated ash	<= 0,1	0,0	%	
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	99,3	%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

28-07-2022

Expiration: 30-11-2025

Conclusion: APPROVED

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