

Certificate of Analysis

Productname: Trimethoprimum
Number of analysis/Inspection Code: 1 / KEUR-183447B
Batchnumber: 20A09-F02-370276
Reference code / No.: 2000 / A-20111910035
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white powder	Conform		
Identification C	Conform	Conform		IR-SPECTRUM
Appearance of solution	<=BY7	Conform		5% <i>m/V</i>
Related substances A	Conform	Conform		HPLC
Any impurity	<=0,1	<0,02	%	
Total impurities	<=0,2	<0,02	%	
Related substances B	Conform	Conform		HPLC
Any impurity	<=0,1	0,0	%	
Total impurities	<=0,2	0,0	%	
Impurity K	<=5	Conform	ppm	GC; data producer
Loss on drying	<=1,0	0,2	%	105 °C 4h
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Trimethoprim	98,5 - 101,0	99,6	% <i>m/m</i>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
W.L. Chung
Pharmacist - Qualified Person

06/16/20

Expiration: 09-2024

Conclusion: APPROVED

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