

Certificate of Analysis

Productname: Sulfamethoxazolum
Number of analysis/Inspection Code: 1 / KEUR-186444B
Batchnumber: 20G15-F06-373558
Reference code / No.: 2000 / A-20212003025
Analysed according to: PH.EUR10.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	169 - 172	170	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / color <Y5, BY5 or GY5	Conform		1 g / 10 ml NaOH 1M
Acidity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity A	<=0,1	<0,1	%	
Impurity B	<=0,1	<0,1	%	
Impurity C	<=0,1	<0,1	%	
Impurity D	<=0,1	<0,1	%	
Impurity E	<=0,1	<0,1	%	
Impurity F	<=0,1	0,0	%	
Any other impurity	<=0,1	<0,025	%	
Total impurities	<=0,3	<0,3	%	
Loss on drying	<=0,5	0,1	%	105 °C
Sulphated ash	<=0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Sulfamethoxazol	99,0 - 101,0	99,9	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:
Paul Hofman
Pharmacist - Qualified Person

10/19/20

Expiration: 02-2025

Conclusion: APPROVED

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