Certificate of Analysis

Product name: **Sulfamethoxazolum**

Batch number / Weight: **22H23-B16-226714 / 50 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22H23-B16 / INS-22-7294**

Reference Code / No.: **V01635 / A-20212204040**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	169 - 172	170,7	°C	Melting point
Identification B	Conform	Conform		IR-spectrum
Colour of solution	<Y5, BY5 or GY5	Conform		1 g / 10 ml NaOH 1M
Acidity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Impurity A	<=0,1	<0,025	%	
Impurity B	<=0,1	0,04	%	
Impurity C	<=0,1	<0,025	%	
Impurity D	<=0,1	<0,025	%	
Impurity E	<=0,1	<0,025	%	
Impurity F	<=0,1	0,05	%	
Any other impurity	<=0,1	<0,025	%	
Total impurities	<=0,3	0,09	%	
Loss on drying	<=0,5	0,08	%	105 °C
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Sulfamethoxazol	99,0 - 101,0	100,47	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<=1000	0,0	ppm	
Acetone	<=1000	11,0	ppm	
Dichloromethane	<=100	0,0	ppm	
Benzene	<2	0,0	ppm	
Pyridine	<200	0,0	ppm	
Toluene	<890	0,0	ppm	

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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:
Ewelina Gadzinowska
Qualified Person

20-01-2023

Expiration: 31-03-2027

Conclusion: APPROVED

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