

Certificate of Analysis

Product name: **Acetazolamidum**

Batch number / Weight: **22E12-B03-219517 / 100 G**

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

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	<=ref. susp. II / <=Y5 or BY5	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,15	<0,05	%	
Impurity B	<=0,15	0,117	%	
Impurity C	<=0,15	<0,05	%	
Impurity D	<=0,15	0,082	%	
Impurity E	<=0,15	<0,05	%	
Impurity F	<=0,15	0,054	%	
Unspecified impurities	<=0,10	<0,05		
Total impurities	<=0,6	0,25	%	
Sulphates	<=500	<500	ppm	
Loss on drying	<=0,5	0,12	%	
Sulphated ash	<=0,1	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Acetazolamide	98,5 - 101,0	100,12	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Ewelina Gadzinowska
Qualified Person

27-07-2022

Expiration: 31-03-2027

Conclusion: APPROVED

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