

Certificate of Analysis

Productname: Acetazolamidum
Number of analysis/Inspection Code: 1 / KEUR-187548B
Batchnumber: 20B03-F07-373247
Reference code / No.: 3851 / ACT-2001010C
Analysed according to: PH.EUR10.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		UV-spectrum
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	<=ref. susp. II / <=Y5 or BY5	Conform		1 g / 10 ml NaOH 1M
Related substances	Conform	Conform		HPLC
Impurity A	<=0,15	<0,05	%	
Impurity B	<=0,15	0,08	%	
Impurity C	<=0,15	n.d.	%	
Impurity D	<=0,15	0,09	%	
Impurity E	<=0,15	<0,05	%	
Impurity F	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	n.d.	%	
Total impurities	<=0,6	0,2	%	
Sulphates	<=500	Conform	ppm	
Loss on drying	<=0,5	0,2	%	105°C
Sulphated ash	<=0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Acetazolamide	98,5 - 101,0	100,5	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:
 Paul Hofman
 Pharmacist - Qualified Person

12/07/20

Expiration: 12-2024

Conclusion: APPROVED

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