

Certificate of Analysis

Productname: **Albendazolum**
Number of analysis/Inspection Code: 2 / KEUR-185483B
Batchnumber: **20B27-F01-373148**
Reference code / No.: 4208 / AEA003315A
Analysed according to: **PH.EUR10.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Yellow-)white powder	Conform		
IR-spectrum	Conform	Conform		
Appearance of solution	Clear <=BY6	Conform		
Related substances	Conform	Conform		HPLC
Impurity H	<=0,6	<0,05	%	
Impurity F	<=0,5	0,5	%	
Impurity A	<=0,4	0,1	%	
Sum of impurities B and C	<=0,4	0,1	%	
Impurity E	<=0,3	0,1	%	
Impurity D	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	0,06	%	
Total impurities	<=1,3	0,8	%	
Loss on drying	<=0,5	0,2	%	4 h 105 °C; in vacuo
Sulphated ash	<=0,2	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Albendazole	99,0 - 101,0	100,4	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		

Analysis performed by the authorized laboratory Quercus BE.

Release:
Paul Hofman
Pharmacist - Qualified Person

09/03/20

Expiration: 01-2025

Conclusion: APPROVED

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