

## Certificate of Analysis

**Product name:** **Albendazolum**

**Batch number / Weight:** **20B27-F01-219973 / 25 G**

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

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		
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	%	
Total impurities	<=1,3	0,8	%	
Unspecified impurities	<=0,10	0,06	%	
Loss on drying	<=0,5	0,2	%	
Sulphated ash	<=0,2	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Albendazole	99,0 - 101,0	100,4	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
Agnieszka Pszczółka  
Qualified Person

22-04-2022

Expiration: 31-01-2025

Conclusion: APPROVED

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