

Certificate of Analysis

Product name: Theophyllinum (anhydr.) micron
Batch number / Weight: 21G27-B05-213167 / 100 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Crystalline, white powder	Conform		
Particle size	99% <25 µm / 90% <10 µm	Conform		
Identification B	Conform	Conform		
Identification D	<=0,5	Conform	%	
Appearance of solution	Clear / colourless	Conform		
Acidity	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,1	<0,05	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	<0,05	%	
Impurity D	<=0,1	<0,05	%	
Any other impurity	<=0,1	<0,05	%	
Total impurities	<=0,5	<0,05	%	
Loss on drying	<= 0,5	0,05	%	
Sulphated ash	<=0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Theophylline	99,0 - 101,0	99,9	%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

10-12-2021

Expiration: 31-12-2024

Conclusion: APPROVED

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