

## Certificate of Analysis

**Productname:** Theophyllinum (anhydr.) micron  
**Number of analysis/Inspection Code:** 1 / KEUR-187229B  
**Batchnumber:** 20J01-F08-375091  
**Reference code / No.:** 3661 / 19232089  
**Analysed according to:** PHEUR10.2+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Crystalline, white powder	Conform		
Particle size	99% <=25 µm / 90% <=10 µm	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification D	<=0,5	Conform	%	Loss on drying
Appearance of solution	Clear / colourless	Conform		0.67% <sub>m/V</sub>
Acidity	Conform	Conform		
Related substances	Conform	Conform		
Impurity A	<=0,1	<0,1	%	
Impurity B	<=0,1	<0,05	%	
Impurity C	<=0,1	<0,1	%	
Impurity D	<=0,1	<0,05	%	
Any other impurity	<=0,1	<0,05	%	
Total impurities	<=0,5	<0,5	%	
Loss on drying	<= 0,5	0,1	%	105°C
Sulphated ash	<=0,1	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Theophylline	99,0 - 101,0	99,8	% <sub>m/m</sub>	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:  
 Paul Hofman  
 Pharmacist - Qualified Person

11/23/20

Expiration: 06-2023

Conclusion: APPROVED

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