

## Certificate of analysis



Article	2691	Theophyllin-Ethylendiamin-Hydrat, API	
Synonym		Theophyllum et ethylendiaminum hydricum	
Synonym		Theophylline-ethylendiamine-hydrate, API	
Batch	23003143		
Specification	Ph.Eur.11.0		
Production date	10.2023	Retest date	04.2025

Test	Specification	Result	
Characters	According to specification	Complies	
Appearance	According to specification	Complies	
Solubility	According to specification	Complies	
Identification	According to specification	Complies	
IR spectrophotometry	According to specification	Complies	
Melting point (derivative)	248 ... 252 °C	249 °C	
E	According to specification	Complies	
Raman spectrophotometry	According to specification	Not carried out	
Tests	According to specification	Complies	
Appearance of solution	According to specification	Complies	
Related substances	According to specification	Complies	#
Each unspecified impurity	Max. 0.10 %	< 0.05 %	#
Total of all impurities	Max. 0.1 %	0.0 %	#
Water	3.0 ... 8.0 %	4.6 %	
Sulphated ash	Max. 0.1 %	0.0 %	#
Assay (Theophylline)	84.0 ... 87.4 %	86.9 %	
Assay (Ethylendiamine)	13.5 ... 15.0 %	14.3 %	
Correction factor weighing (f, NRF)	1,000	0,952	
Complies specification		Yes	

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Release date	13.12.2023	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	Siegfried PharmaChemikalien Minden GmbH		
Manufacturer batch	23432096		
Manufacturer street	Karlstrasse 15-39, 42-44		
Manufacturer city	32423 Minden		
Manufacturer country	Deutschland		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 23003143 complies specification.

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