

## Certificate of Analysis

**Product name:** **Erythromycinum**  
**Batch number / Weight:** **20A29-B15-219979 / 25 G**  
**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow powder	Conform		
Identification A	Conform	Conform		
Solubility	acc. to Ph. Eur.	Conform		
Related substances	Conform	Conform		
Impurity A	$\leq 2,0$	Conform	%	
Impurity B	$\leq 2,0$	Conform	%	
Impurity D	$\leq 1,0$	Conform	%	
Impurity C	$\leq 3,0$	1,25	%	
Impurity E	$\leq 1,0$	Conform	%	
Impurity F	$\leq 1,0$	Conform	%	
Impurity H	$\leq 1,0$	Conform	%	
Impurity L	$\leq 0,4$	$< 0,2$	%	
Impurity M	$\leq 1,0$	Conform	%	
Any impurity	$\leq 0,4$	0,26	%	
Total impurities	$\leq 7,0$	3,11	%	
Thiocyanate	$\leq 0,3$	0,03	%	
Water (Karl Fischer)	$\leq 6,5$	1,38	%	
Sulphated ash	$\leq 0,2$	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Erythromycine (A+B+C)	93,0 - 102,0 (anhydrous substance)	96,28	%m/m	
Erythromycine B	$\leq 5,0$ (anhydrous substance)	0,00	%	
Erythromycine C	$\leq 5,0$ (anhydrous substance)	0,22	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Dominika Soltysik

Qualified Person

21-04-2022

Expiration: 31-07-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.