

## Certificate of Analysis

**Product name:** **Erythromycinum**  
**Batch number / Weight:** **20A29-B15-210436 / 100 G**  
**Analysed according to:** **Ph.Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow powder	Conform		
	slightly hygroscopic	Conform		
Identification A	Conform	Conform		
Related substances	Conform	Conform		
Impurity A,B	$\leq 2,0$	0,82	%	
Impurity C	$\leq 3,0$	1,25	%	
Impurities D, E, F, H, M	$\leq 1,0$	0,15	%	
Impurity L	$\leq 0,4$	$< 0,2$	%	
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:  
 Ewelina Gadzinowska  
 Qualified Person

03-02-2021

Expiration: 31-07-2024

Conclusion: APPROVED

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