

## Certificate of Analysis

**Product name:** **Erythromycinum**  
**Batch number / Weight:** **19I20-B03-194970 / 10 G**  
**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow powder slightly hygroscopic	Conform Conform		
Identification A	Conform	Conform		
Related substances	Conform	Conform		
Impurity A,B	<= 2,0	<0,2	%	
Impurity C	<=3,0	1,16	%	
Impurities D, E, F, H, M	<= 1,0	<0,2	%	
Impurity L	<=0,4	<0,2	%	
Any impurity	<=0,4	0,28	%	
Total impurities	<=7,0	3,04	%	
Thiocyanate	<=0,3	0,02	%	
Water (Karl Fischer)	<=6,5	1,73	%	
Sulphated ash	<=0,2	0,02	%	
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	96,89	%m/m	
Erythromycine B	<=5,0	0,08	%	
Erythromycine C	<=5,0	0,23	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:  
Dorota Sutkowska  
Qualified Person

15-01-2020

Expiration: 31-07-2024

Conclusion: APPROVED



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