

Certificate of Analysis

Product name: **Erythromycinum**
Batch number / Weight: **19B19-B05-191844 / 25 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	$\leq 2,0$	$<0,2$	%	
Impurity C	$\leq 3,0$	$<0,2$	%	
Impurities D, E, F, H, M	$\leq 1,0$	$<0,2$	%	
Impurity L	$\leq 0,4$	$<0,2$	%	
Any impurity	$\leq 0,4$	$<0,2$	%	
Total impurities	$\leq 7,0$	$<0,2$	%	
Thiocyanate	$\leq 0,3$	0,02	%	
Water (Karl Fischer)	$\leq 6,5$	0,9	%	
Sulphated ash	$\leq 0,2$	0,03	%	
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	95,6	%m/m	
Erythromycine B	$\leq 5,0$	0,4	%	
Erythromycine C	$\leq 5,0$	0,8	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dorota Sutkowska
 Qualified Person

26-09-2019

Expiration: 22-09-2022

Conclusion: APPROVED



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