

Certificate of Analysis

Product name: Erythromycinum
Batch number / Weight: 20D30-B14-201687 / 100 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow powder slightly hygroscopic	Conform		
Identification A	Conform	Conform		
Related substances	Conform	Conform		
Impurity A,B	$\leq 2,0$	0,65(A)+0,89(B)	%	
Impurity C	$\leq 3,0$	1,37	%	
Impurities D, E, F, H, M	$\leq 1,0$	Conform	%	
Impurity L	$\leq 0,4$	$< 0,2$	%	
Any impurity	$\leq 0,4$	$< 0,2$	%	
Total impurities	$\leq 7,0$	3,07	%	
Thiocyanate	$\leq 0,3$	0,02	%	
Water (Karl Fischer)	$\leq 6,5$	1,34	%	
Sulphated ash	$\leq 0,2$	0,05	%	
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	100,14	%m/m	
Erythromycine B	$\leq 5,0$	0,00	%	
Erythromycine C	$\leq 5,0$	0,29	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

20-08-2020

Expiration: 28-02-2023

Conclusion: APPROVED

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