

Certificate of Analysis

Product name: Erythromycinum
Batch number / Weight: 20A29-B15-197332 / 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	<= 2,0	<2,0	%	
Impurity C	<=3,0	1,25	%	
Impurities D, E, F, H, M	<= 1,0	0,15	%	
Impurity L	<=0,4	<0,2	%	
Any impurity	<=0,4	0,26	%	
Total impurities	<=7,0	3,11	%	
Thiocyanate	<=0,3	0,03	%	
Water (Karl Fischer)	<=6,5	1,38	%	
Sulphated ash	<=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	96,28	%m/m	
Erythromycine B	<=5,0	0,00	%	
Erythromycine C	<=5,0	0,22	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Dominika Sołtysik
 Qualified Person

23-03-2020

Expiration: 31-07-2024

Conclusion: APPROVED



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