

Certificate of Analysis

Product name: Erythromycinum
Batch number / Weight: 19I20-B03-194972 / 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	$\leq 2,0$	$<2,0$	%	
Impurity C	$\leq 3,0$	1,16	%	
Impurities D, E, F, H, M	$\leq 1,0$	$<0,2$	%	
Impurity L	$\leq 0,4$	$<0,2$	%	
Any impurity	$\leq 0,4$	0,28	%	
Total impurities	$\leq 7,0$	3,04	%	
Thiocyanate	$\leq 0,3$	0,02	%	
Water (Karl Fischer)	$\leq 6,5$	1,73	%	
Sulphated ash	$\leq 0,2$	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	$\leq 5,0$	0,08	%	
Erythromycine C	$\leq 5,0$	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

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