

Certificate of Analysis

Product name: **Erythromycinum**

Batch number / Weight: **22A15-B11-219926 / 25 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		
Specific optical rotation	-71 - -78 (anhydrous substance)	-73,6		
Related substances	Conform	Conform		
Impurity A	<= 2,0	0,57	%	
Impurity B	<= 2,0	0,92	%	
Impurity D	<= 1,0	0,24	%	
Impurity C	<=3,0	1,00	%	
Impurity E	<= 1,0	<0,2	%	
Impurity F	<= 1,0	<0,2	%	
Impurity H	<= 1,0	0,16	%	
Impurity L	<=0,4	<0,2	%	
Any impurity	<=0,4	<0,2	%	
Total impurities	<=7,0	2,89	%	
Thiocyanate	<=0,3	0,03	%	
Water (Karl Fischer)	<=6,5	1,22	%	
Sulphated ash	<=0,2	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Dichloromethane	<=600	4,4	ppm	
Assay Erythromycine (A+B+C)	93,0 - 102,0 (anhydrous substance)	96,17	%m/m	
Erythromycine B	<=5,0 (anhydrous substance)	0,06	%	
Erythromycine C	<=5,0 (anhydrous substance)	0,12	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Dominika Soltysik

Qualified Person

26-04-2022

Expiration: 31-08-2024

Conclusion: APPROVED

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