Certificate of Analysis

Product name: **Erythromycinum**

Batch number / Weight: **22E17-B04-226999 / 10 G**

Analysed according to: **Ph.Eur.11.0**

Number of analysis / Inspection Code **22E17-B04 / INS-22-4056**

Reference Code / No.: **V00596 / EBS/21-031**

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
Residual solvents				
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

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:
Dominika Sołtysik
Qualified Person

14-01-2023

Expiration: 31-08-2024

Conclusion: APPROVED

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