

Certificate of Analysis

Productname: Erythromycinum micronisatum
Number of analysis/Inspection Code: 1 / KEUR-180651B
Batchnumber: 19L18-F02-367781
Reference code / No.: 4125 / CEPEB 031 K 19 P
Analysed according to: PHEUR10.0+

Tests	Requirement	Result	Unit	Standard remark
Appearance	White to weak yellow powder or colorless or weak yellow cry	Conform		Slightly hygroscopic
Particle size	>=95% <20 µm	Conform		
Identification A	Conform	Conform		IR-spectrum
Related substances	Conform	Conform		HPLC
Impurity C	<=3,0	1,0	%	
Impurity A,B	<=2,0	<=0,7	%	
Impurities D, E, F, H, M	<=1,0	<=0,2	%	
Impurity L	<=0,4	<0,2	%	
Any impurity	<=0,4	0,2	%	
Total impurities	<=7,0	2,4	%	
Thiocyanate	<=0,3	0,0	%	
Water (Karl Fischer)	<=6,5	1,4	%	
Sulphated ash	<=0,2	0,0	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Erythromycine (A+B+C)	93,0 - 102,0	99,5	%m/m	Anhydrous
Erythromycine B	<=5,0	0,2	%	
Erythromycine C	<=5,0	0,2	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
dr. M.J. Vincenten - van Maanen
Pharmacist - Qualified Person

02/21/20

Expiration: 10-2022

Conclusion: APPROVED

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