

Certificate of Analysis

Product name: Chloramphenicolum
Batch number / Weight: 21C04-B04-211006 / 25 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white, greyish-white or yellowish-white powder	Conform		
Identification A	Conform	Conform		
Acidity or alkalinity	Conform	Conform		
Specific optical rotation	+18,5 - +20,5	+20,0		
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	0,073	%	
Total impurities	<=0,5	0,14	%	
Chlorides	<=100	Conform	ppm	
Loss on drying	<=0,5	0,06	%	
Sulphated ash	<=0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Chloramphenicol	97,5 - 102,0 (dried substance)	99,84	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

30-04-2021

Expiration: 05-01-2025

Conclusion: APPROVED

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