

Certificate of Analysis

Product name: **Chloramphenicolum**
Batch number / Weight: **22B02-B09-222739 / 100 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22B02-B09 / INS-22-2241**
Reference Code / No.: **V01863 / DY0092000001**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white, greyish-white or yellowish-white powd	Conform		
Identification A	Conform	Conform		
Acidity or alkalinity	Conform	C		
Specific optical rotation	+18,5 - +20,5	+19,8		
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	0,086	%	
Total impurities	<=0,5	0,14	%	
Chlorides	<=100	C	ppm	
Loss on drying	<=0,5	0,05	%	
Sulphated ash	<=0,1	0,02	%	
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)	100,10	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Methanol	<= 3000	6,1	ppm	
Ethanol	<= 5000	2,8	ppm	
Isopropanol	<= 5000	7,5	ppm	
Chlorobenzene	<= 360	0,0	ppm	
Benzene	<= 2	0,0	ppm	

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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:
Ewelina Gadzinowska
Qualified Person

24-08-2022

Expiration: 05-01-2025

Conclusion: APPROVED

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