

## Certificate of Analysis

**Product name:** **Chloramphenicolum EU**

**Batch number / Weight:** **24D11-B05 / KG**

**Analysed according to:** **Ph.Eur. 04/2019:0071**

**Number of analysis / Inspection Code /**

**Reference Code / No.:** **V01863 / DY0092200140**

Tests	Requirement	Result	Unit	Standard remark
Protocol number		409/SN/0424		
Appearance	Fine, white, greyish-white or yellowish-white powder	Conform		
Identification A	Conform	Conform		
Acidity or alkalinity	Conform	0,05 (NaOH)	ml	
Specific optical rotation	+18,5 - +20,5	+20,1		
Related substances	Conform	Conform		
Impurity A	<=0,2	<0,05	%	
Unspecified impurities	<=0,10	0,087	%	
Total impurities	<=0,5	0,22	%	
Chlorides	<=100	<100	ppm	
Loss on drying	<=0,5	0,08	%	
Sulphated ash	<=0,1	0,00	%	
Assay Chloramphenicol	97,5 - 102,0 (dried substance)	99,80	%m/m	
Correction factor		1,003		
Residual solvents				
Methanol	<= 3000	30	ppm (dp)	
Ethanol	<= 5000	0	ppm (dp)	
Isopropanol	<= 5000	0	ppm (dp)	
Chlorobenzene	<= 360	0	ppm (dp)	
Benzene	<= 2	0	ppm (dp)	
Additional requirements				
Northeast Pharmaceutical Group				
Residual solvents				
Methanol		4,0	ppm	
Ethanol		4,0	ppm	
Isopropanol		22,3	ppm	

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Chlorobenzene  
Benzene

<= 360

0,0 ppm  
0,0 ppm

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:

Magdalena Łatak

Quality Control Supervisor/Speciali

18-04-2024

Expiration: 25-06-2027

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

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