

Certificate of Analysis

Product name: **Metronidazolum apyrogen**

Batch number / Weight: **23C02-B05-230418 / 50 G**

Analysed according to: **Ph.Eur.11.1**

Number of analysis / Inspection Code **23C02-B05 / INS-23-2043**

Reference Code / No.: **V00610 / C04-220144**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or yellowish crystalline powder	Conform		
Identification C	acc.to Ph.Eur.	Conform		
Rozpuszczalność	trudno rozpuszcza się w wodzie	Conform		
Appearance of solution	acc.to Ph.Eur.	Conform		
Related substances	acc. to Ph. Eur.			
Any impurity	<=0,1	0,011	%	
Total impurities	<=0,2	0,02	%	
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	nie więcej niż 0,05%	0,011	%	
Loss on drying	<=0,5	0,06	%	
Sulfated ash	<=0,1	0,01	%	
Assay	99,0 - 101,0 (dried substance)	100,02	%	
Total aerobic microbial count (TA)		<1	CFU/g	
Total yeasts and moulds (TYMC)		<1	CFU/g	
Bacterial endotoxins	<=0,35	<0,35	IU/mg	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
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, EI Spol, CBMiA

Release:
Dominika Soltysik
Qualified Person

16-06-2023

Expiration: 31-12-2026

Conclusion: APPROVED

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