

Certificate of Analysis

Product name: **Metronidazolum**

Batch number / Weight: **23H31-B08-237990 / 250 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23H31-B08 / INS-23-6783**

Reference Code / No.: **V00610 / C04-230619**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or yellowish crystalline powder	Conform		
Identification C	acc.to Ph.Eur.	Conform		
Appearance of solution	acc.to Ph.Eur.	Conform		
Related substances	acc.to Ph.Eur.	Conform		
Any impurity	$\leq 0,1$	0,01	%	
Total impurities	$\leq 0,2$	0,01	%	
Loss on drying	$\leq 0,5$	0,42	%	
Sulfated ash	$\leq 0,1$	0,00	%	
Assay	99,0 - 101,0 (dried substance)	99,88	%	
Total aerobic microbial count (TA)	$< 10^3$	< 1	CFU/g	
Total yeasts and moulds (TYMC)	$< 10^2$	< 1	CFU/g	
Bacterial endotoxins	$\leq 0,35$	$< 0,35$	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 FAPL, EISpol, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

09-04-2024

Expiration: 31-05-2028

Conclusion: APPROVED

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