Certificate of Analysis

Product name: **Paracetamolum (500-90)**

Batch number / Weight: **21J08-B05-231050 / 100 G**

Analysed according to: **Ph.Eur.11**

Number of analysis / Inspection Code **21J08-B05 / INS-21-6375**

Reference Code / No.: **V01442 / 22008866**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, white, crystalline powder	Conform		
Apparent volume	0,35 - 0,55	0,45	g / ml	
Tapped density	0,65 - 0,80	0,671	g / ml	
Identification B	Conform	Conform		
Related substances	Conform	Conform		
Impurity J	<=10	<10	%	
Impurity K	<=50	<25	ppm	
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=0,2	<0,2	%	
Loss on drying	<= 0,5	0,06	%	
Sulphated ash	<= 0,1	0,05	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Paracetamol	99,0 - 101,0	100,2	%m/m	
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 lab,CBMiA

Release:
Dominika Sołtysik
Qualified Person

22-06-2023

Expiration: 31-08-2025

Conclusion: APPROVED

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

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