

Certificate of Analysis

Product name: Paracetamolum (500-90)

Batch number / Weight: 24C12-B16 / KG

Analysed according to: Ph.Eur. 01/2014:1615

Number of analysis / Inspection Code /

Reference Code / No.: V01442 / 223121540

Tests	Requirement	Result	Unit	Standard remark
Protocol no		661/S/0324		
Appearance	Fine, white, crystalline powder	Conform		
Identification B	Conform	Conform		
Related substances	Conform	Conform		
Impurity J	<=10	0,6	ppm	
Impurity K	<=50	0,6	ppm	
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=0,2	0,00	%	
Loss on drying	<= 0,5	0,10	%	
Sulphated ash	<= 0,1	0,00	%	
Assay Paracetamol	99,0 - 101,0	100,56	%m/m	
Correction factor		1,001		

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

17-04-2024

Expiration: 31-12-2028

Conclusion: APPROVED

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