

Certificate of Analysis

Productname: Paracetamol (500-90)
Number of analysis/Inspection Code: 1 / KEUR-188682B
Batchnumber: 20J27-F04-375756
Reference code / No.: 4109 / 22008866
Analysed according to: PHEUR10.2+

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Particle size	97% <500 µm	99	%	Sieve analysis
Particle size	60% >90 µm	93	%	
Apparent volume	0,35 - 0,55	0,45	g / ml	Untapped
Identification B	Conform	Conform		IR-spectrum
Related substances	Conform	Conform		HPLC
Impurity J	<=10	<10	ppm	
Impurity K	<=50	<25	ppm	
Unspecified impurities	<=0,05	<0,03	%	
Total impurities	<=0,2	<0,2	%	
Loss on drying	<= 0,5	0,1	%	105 °C
Sulphated ash	<= 0,1	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Paracetamol	99,0 - 101,0	100,2	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Paul Hofman
Pharmacist - Qualified Person

02/11/21

Expiration: 08-2025

Conclusion: APPROVED

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