

Certificate of Analysis

Product name: **Papaverini hydrochloridum**
Batch number / Weight: **23D17-B05-239633 / 100 G**
Producer / Producer Batch Number: Recordati S.p.A - Campoverde / 23100151
Analysed according to: **Ph.Eur.11**

Number of analysis / Inspection Code **23D17-B05 / INS-23-3568**

Reference Code / No.: **V01398 / 23100151**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or (almost) white crystals	Conform		
Identification A	Conform	Conform		
Identification D	White	Conform		
Appearance of solution	White	Conform		
pH	3,0 - 4,0	3,47		
Related substances	Conform	Conform		
Any other impurity	$\leq 0,1$	$< 0,05$	%	
Total impurities	$\leq 0,5$	0,00	%	
Loss on drying	$\leq 0,5$	0,07	%	
Sulphated ash	$\leq 0,1$	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 101,0	100,06	%m/m	

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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:

Agnieszka Pszczółka

Qualified Person

20-05-2024

Expiration: 13-03-2028

Conclusion: APPROVED

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