

Certificate of Analysis

Product name: Papaverini hydrochloridum
Batch number / Weight: 25E15-B11-014990 / 100 g
Producer / Producer Batch Number: Recordati S.p.A - Campoverde / 25100099
Analyzed according to: Ph. Eur.11.8
Number of Analysis / Certificate no.: 25E15-B11 / QO0022896

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or (almost) white crystals	Conform		
Identification	A, D	Conform		
Appearance of solution	Clear / <=BY6	Conform		
pH	3,0 - 4,0	3,10		
Related substances	Conform	Conform		
Any impurity	<= 0,1	0,06	%	
Total impurities	<= 0,5	0,06	%	
Loss on drying	<= 0,5	0,04	%	
Sulfated ash	<= 0,1	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 101,0	99,44	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
TAMC	<= 10 ³	< 10 ²	cfu/g	
TYMC	<= 10 ²	< 10 ¹	cfu/g	

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 FSNE lab

Release:

21-10-2025
 Agnieszka Pszczółka
 Qualified Person

Expiration: 18-2-2030

Conclusion: APPROVED

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