

Certificate of Analysis

Product name: Cyproheptadini HCl 1,5-hydr.
Batch number / Weight: 25B01-B09-011886 / 5 g
Producer / Producer Batch Number: Vasudha Pharma Chem Limited - Unit II / BCYPH/2411086
Analyzed according to: Ph. Eur. 11.8
Number of Analysis / Certificate no.: 25B01-B09 / QO0017861

	Requirement	Result	Unit	Standard remark
Appearance	White or slightly yellow, crystalline powder	Conform		
Identification	A, B	Conform		
Acidity	$\leq 0,15$ NaOH (0,40 g/l)	0,05	ml	
Related substances	Conform	Conform		
Impurity A	$\leq 0,15$	0,000	%	
Impurity B	$\leq 0,15$	0,000	%	
Impurity C	$\leq 0,15$	0,000	%	
Unspecified impurities	$\leq 0,10$	0,000	%	
Total impurities	$\leq 0,5$	$< 0,05$	%	
Water (Karl Fischer)	7,0 - 9,0	7,92	% m/m	
Sulfated ash	$\leq 0,1$	0,07	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	98,5 - 101,0	100,31	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	Conform		DP
Metallic residues	CHMP/ICH/353369/2013	Conform		DP

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, Espefa

Release:

16-7-2025
Dominika Sołtysik
Qualified Person

Expiration: 31-10-2029

Conclusion: APPROVED

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