Certificate of Analysis

Product name: Doxycyclini hyclas
Batch number / Weight: 26A15-B03-021152 / 10 g
Producer / Producer Batch Number: Yancheng Suhai Pharmaceutical Co., Ltd / H202501020
Analyzed according to: Ph.Eur. 12.1
Number of Analysis / Certificate no.: 26A15-B03 / QO0030608

	Requirement	Result	Unit	Standard remark
Appearance	Yellow, hygroscopic,crystalline powder	Conform		
Identification	A, B, C	Conform		
pH	2,0-3,0	2,5		
Absorbance	<=0,07	0,009		
Related substances	Conform	Conform		
Impurity A	<=2,0	1,4	%	
Impurity F	<=1,2	0,9	%	
Impurity B	<=0,5	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Any other impurity	<=0,10	0,000	%	
Total impurities	<=3,0	2,3	%	
Ethanol	4,3-6,0	5,0	%	
Water	1,4 - 2,8	2,1	%	
Sulfated ash	<=0,4	0,2	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	95,0 - 102,0	97,6	% m/m	
TSE/BSE-statement:	EMA/410/01 guidance compliant – no contamination	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 Espefa

Release:

30-3-2026
Ewelina Gadzinowska
Qualified Person

Expiration: 20-1-2029
Conclusion: APPROVED

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

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