Certificate of Analysis

Product name: Griseofulvinum
Batch number / Weight: 25B07-B13-008594 / 100 g
Producer / Producer Batch Number: Inner Mongolia Glint Pharmaceutical Co., Ltd / C007-240409
Analyzed according to: Ph.Eur.11.7
Number of Analysis / Certificate no.: 25B07-B13 / QO0013821

	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish-white powder	Conform		
Identification	Conform	Conform		
Melting point	about 220	219,6	°C	
Appearance of solution	Clear / <=Y4	Conform		
Acidity	<= 1,0 ml of NaOH (0,02M)	0,45	ml	
Specific optical rotation	(+354) - (+364)	+361,4		
Related substances	Acc. to Ph. Eur.	Conform		
Impurity B	<= 3,0	1,03	%	
Impurity A	<= 2,0	0,50	%	
Impurity C	<= 0,75	0,332	%	
Unspecified impurities	<= 0,15	<0,10	%	
Total impurities	<= 5,0	1,86	%	
Loss on drying	<= 1,0	0,11	%	
Sulfated ash	<= 0,2	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	94,0-102,0	98,58	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	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

Release:

7-4-2025
Dominika Sołtysik
Qualified Person

Expiration: 28-3-2028
Conclusion: APPROVED

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

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