

Certificate of Analysis

Product name: **Griseofulvinum**
Batch number / Weight: **22K14-B07-215618 / 50 G**
Analysed according to: **Ph. Eur. 10.8**
Number of analysis / Inspection Code **22K14-B07 / INS-22-9549**
Reference Code / No.: **V02119 / HH-220303 EP10**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or pale yellow powder	Conform		
Identification A	Conform	Conform		
Melting point	about 220	221,3	°C	
Appearance of solution	Clear / <=Y4	Conform		
Acidity	Conform	0,40 ml NaO		
Specific optical rotation	+354 - +364	+357,4		
Related substances	Conform	Conform		
Impurity B	<=3,0	1,32	%	
Impurity A	<=2,0	0,36	%	
Impurity C	<=0,75	0,354	%	
Unspecified impurities	<=0,15	<0,10	%	
Total impurities	<=5,0	2,04	%	
Loss on drying	<=1,0	0,08	%	
Sulphated ash	<=0,2	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Griseofulvine	97,0 - 102,0	97,72	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Ethanol	<= 5000	<5000	ppm	
Acetone	<= 5000	<5000	ppm	
Dichloromethane	<= 600	<600	ppm	

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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

Release:
Ewelina Gadzinowska
Qualified Person

28-12-2022

Expiration: 27-02-2026

Conclusion: APPROVED

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