

**GRISEOFULVINUM 50 g**

Lot No.: 23C02-AP23092

Autorisation :	1890IR6170	Date Of Analysis :	02/03/2023
Analytical Reference :	Ph. Eur. (04/2019:0182)	Production Number :	250423-0110123
CNK :	4688-032	Expiry Date :	08/2026

**ANALYTICAL TESTS**

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or yellowish-white powder	Complies
Melting Point	About 220 °C	221 °C
IDENTIFICATION	SPECIFICATION	RESULT
Identification	Complies	Complies
TESTS	SPECIFICATION	RESULT
Acidity	≤ 1.0 mL of 0.02 M NaOH 0.02 M	0.4 mL of 0.02 M NaOH
Specific optical rotation	+354 / +364	+359
Related substances		
Impurity B	≤ 3.0 %	1.5 %
Impurity A	≤ 2.0 %	< 0.10 %
Impurity C	≤ 0.75 %	0.26 %
Unspecified impurities	≤ 0.15 %	< 0.10 %
Total impurities	≤ 5.0 %	1.8 %
Loss of drying	≤ 1.0 %	< 0.01 %
Sulfated ash	≤ 0.2 %	0.04 %
ASSAY	SPECIFICATION	RESULT
Assay	94.0 – 102.0 %	95.2 %

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST:

**Joran Smout**  
(Signature)

Digitally signed by Joran Smout (Signature)  
Date: 2023.07.17 12:29:49 +02'00'