

CERTIFICATE OF ANALYSIS

Product : GRISEOFULVIN

 Product number
 : G0167

 Batch number
 : 010296

 Date of production
 : 12-01-2014

 Date of analysis
 : 15-01-2014

 Date of expiry
 : 31-01-2018

Packaging and storage : store at room temperature

Appearance	SPECIFICATION white or yellowish-white microfine powder	RESULT complies	UNITS	REMARKS
Melting point	approx. 220	218.5 - 219.5	°C	
Identification:				
- A (IR-spectrum)	conform	complies		
- B (colour reaction)	conform	complies		
Appearance of solution	clear and colour \leq ref. sol. Y_4	complies		7.5 % in DMF
Acidity	≤ 1.0	0.6		0,02N NaOH/0.25 g
Specific optical rotation	+354 to +364	358	0	1 % DMF
Related substances	conform	complies		GC
Substances soluble in light	≤ 0.2	0.1	%	
petroleum				
Loss on drying	≤ 1.0	0.11	%	105 °C
Sulphated ash	≤ 0.2	0.1	%	
Assay	> 97	98.6	%	dried substance

This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

drs. M. van Wissen, pharmacist

Department of Quality Control Duchefa B.V.

Date: 01-04-2014

The buyer is responsible to test each batch to ensure the product is suitable for its specific purpose.