

CERTIFICATE OF ANALYSIS

METHOTREXATE

M0130

018867

Product

Product number Batch number Date of production

15-12-2021 Date of analysis 28-12-2022 Date of expiry 31-12-2026

Packaging and storage

in a well closed container, protected from light

Appearance	SPECIFICATION yellow or orange, crystalline powder	RESULT complies	UNITS	REMARKS hygroscopic
Identification:				
- A (IR spectrum)	conform	complies		
Related substances	conform	complies		
(R)-Methotrexate	≤ 3.0	0.3	%	
Residual solvents:				
- Acetone	500	1	ppm	
- Methanol	500	< 1	ppm	
- Dimethylformamide	200	< 48	ppm	
Water	≤ 13.0	10.8	%	
Sulphated ash	≤ 0.1	0.1	%	
Assay	97.0 - 102.0	100.0	%	

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

Conclusion: approved

Released by:

J. van der Eem, MSc, pharmacist

Department of Quality Control Duchefa B.V.

Date: 08-11-2024

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

Duchefa Biochemie B.V.