

CERTIFICATE OF ANALYSIS

Product : **METHOTREXATE**
 Product number : M0130
 Batch number : 016884
 Date of production : 11-01-2020
 Date of analysis : 06-02-2020
 Date of expiry : 31-01-2025

Packaging and storage : in a well closed container, protected from light

	SPECIFICATION	RESULT	UNITS	REMARKS
Appearance	yellow or orange, crystalline powder	complies		hygroscopic
Identification:				
- A (IR spectrum)	conform	complies		
Related substances	conform	complies		HPLC
(R)-Methotrexate	≤ 3.0	< 0.3	%	HPLC
Residual solvents:				
- Acetone	500	< 1	ppm	
- Methanol	500	1	ppm	
- Dimethylformamide	200	21	ppm	
Heavy metals	≤ 20	< 20	ppm	
Water	≤ 13.0	12.0	%	Karl Fischer
Sulphated ash	≤ 0.1	0.01	%	
Assay	97.0 – 102.0	97.7	%	anhydrous substance

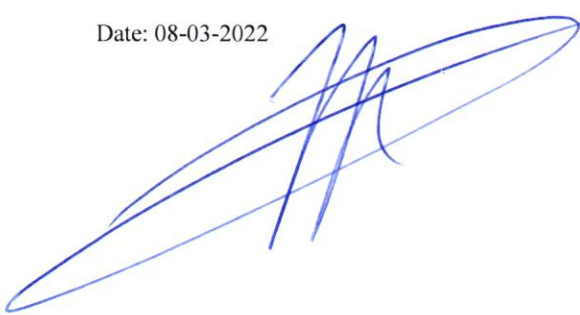
This certificate of analysis is conform the results of the manufacturer.

Conclusion: approved

Released by:

drs. M. van Wissen, pharmacist
 Department of Quality Control Duchefa B.V.

Date: 08-03-2022



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

Duchefa Biochemie B.V.