

## CERTIFICATE OF ANALYSIS

Product : **METHOTREXATE**  
 Product number : M0130  
 Batch number : 016113  
 Date of production : 05-12-2017  
 Date of analysis : 06-09-2018  
 Date of expiry : 31-12-2022

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

	<b>SPECIFICATION</b>	<b>RESULT</b>	<b>UNITS</b>	<b>REMARKS</b>
Appearance	yellow or orange, crystalline powder	complies		hygroscopic
Identification:				
- A (IR spectrum)	conform	complies		
Related substances	conform	complies		HPLC
(R)-Methotrexate	≤ 3.0	< 0.1	%	HPLC
Residual solvents:				
- Acetone	500	< 1	ppm	
- Methanol	500	2	ppm	
- Dimethylformamide	200	44	ppm	
Heavy metals	≤ 20	< 20	ppm	
Water	≤ 13.0	11.64	%	Karl Fischer
Sulphated ash	≤ 0.1	0.09	%	
Assay	97.0 – 102.0	99.4	%	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: 07-04-2021



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

Duchefa Biochemie B.V.