

CERTIFICATE OF ANALYSIS

Product : **METHOTREXATE**
Product number : M0130
Batch number : 014369
Date of production : 10-11-2016
Date of analysis : 25-11-2016
Date of expiry : 30-11-2021

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	< 3.0	%	HPLC
Residual solvents:				
- Acetone	500	< 1	ppm	
- Methanol	500	2	ppm	
- Dimethylformamide	200	28	ppm	
Heavy metals	≤ 20	< 20	ppm	
Water	≤ 13.0	11.31	%	Karl Fischer
Sulphated ash	≤ 0.1	0.05	%	
Assay	97.0 – 102.0	99.84	%	anhydrous substance

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

Conclusion: approved

Released by:

drs. Q. de Hoog, pharmacist
Department of Quality Control Duchefa B.V.

Date: 20-02-2019

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