

CERTIFICATE OF ANALYSIS

Product : **METHOTREXATE**
 Product number : M0130
 Batch number : 013330
 Date of production : 04-11-2015
 Date of analysis : 11-01-2016
 Date of expiry : 30-11-2020
 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	0.27	%	HPLC
Residual solvents:				
- Acetone	500	< 1	ppm	
- Methanol	500	5	ppm	
- Dimethylformamide	200	13	ppm	
Heavy metals	≤ 50	< 20	ppm	
Water	≤ 13.0	10.40	%	Karl Fischer
Sulphated ash	≤ 0.1	0.04	%	
Assay	98.0 – 102.0	98.7	%	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: 15-11-2017



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