

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

Appearance Identification:	SPECIFICATION yellow or orange, crystalline powder	RESULT complies	UNITS	REMARKS hygroscopic
- 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.

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