

CERTIFICATE OF ANALYSIS

Product : **OXYTETRACYCLINE HYDROCHLORIDE**
 Product number : O0140
 Batch number : 008794
 Date of analysis : 30-05-2012
 Date of expiry : 31-03-2014

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

	SPECIFICATION	RESULT	UNITS	REMARKS
Description	yellow, crystalline powder, hygroscopic	complies		
Solubility	soluble in water, slightly soluble in alcohol	complies		
Identity:				
- A (TLC)	conform	complies		
- B (reaction with sulphuric acid)	conform	complies		
- C (chloride)	conform	complies		
pH	2.3 – 2.9	2.6		1% in H ₂ O
Specific optical rotation	-188 – -200	-194.6	°	1% in 0.1N HCl, dried substance
Specific Absorbance	270 – 290	281.2		353 nm
Light-absorbing impurities	conform	complies		
Related substances	conform	complies		HPLC
Heavy metals	≤ 50	complies	ppm	
Water	≤ 2.0	0.85	%	KF
Sulphated ash	≤ 0.5	0.1	%	
Assay	95.0 – 102.0	99.8	%	HPLC, dried 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: 03-12-2013

