

FAGRON

FARMADENT d.o.o,  
 Mlinarikova ul. 6  
 2000 Maribor  
 Režija: FINS DRAGO

Datum prejema: 30.11.15  
 Pregledat: MAROLT Robert, mag. farm., spec.  
 Datum pregleda: 2.2.2015

**Certificate of Analysis**

**Productname:** Oxytetracyclini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-115826B  
**Batchnumber:** 14I22-B01-301462 ✓  
**Reference code / No.:** 2637 / 4-49732A-2  
**Analysed according to:** PH.EUR 8.2

Tests	Requirement	Result	Unit	Standard remark
Appearance	Fine, yellow, crystalline powder	Conform		
	hygroscopic	Conform		
Identification A	Conform	Conform		TLC
Identification B	Deep red / yellow	Conform		
Identification C	Conform	Conform		Chloride
pH	2,3 - 2,9	2,5		1% <i>m/V</i>
Specific optical rotation	-188 - -200	-188	°	1% <i>m/V</i> in 0.1M HCl; watervrij
Specific absorbance	270 - 290	274		353 nm
Lightabsorbing impurities	E430 <0,50	0,16		Anhydrous
Lightabsorbing impurities	E490 <0,20	0,02		Anhydrous
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	<0,5	%	
Impurity B	<=2,0	<2,0	%	
Impurity C	<=2,0	<2,0	%	
Total impurities D, E and F	<=2,0	<2,0	%	
Heavy metals	<=50	Conform	ppm	
Water (Karl Fischer)	<=2,0	1,2	%	
Sulphated ash	<=0,5	0,0	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Oxytetracycline hydrochloride	95,0 - 102,0	98,3	% <i>m/m</i>	Anhydrous
Endotoxins	<= 0,4	Conform	IU/mg	Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Eurofins.

Release:  
 Drs. M.V. Garcia Alia  
 Pharmacist - QA Manager / QP

12/11/14

Expiration: 08-2016 ✓

Conclusion: APPROVED