



## Certificate of Analysis

FARMADENT d.o.o.  
Minarikova ul. 6  
2000 Maribor  
Prejel: FUJS DRAGO  
*Za: Poycin*  
Datum prejema: *30.10.2013*  
Pregledal: *MAROLT Robert, mag. farm., spec.*  
Datum pregleda: *4.11.2013*

Productname: **Oxytetracyclini hydrochloridum**  
Number of analysis/Inspection Code: 1 / KEUR-95788B  
Batchnumber: **13C27-B01-281732** ✓  
Reference code / No.: 2624 / 3-38907A  
Analysed according to: **PH.EUR 7.7**

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	Yellowish white	Conform		Chloride
pH	2,3 - 2,9	2,5		1% <i>m/V</i>
Specific optical rotation	-188 - -200	-192	°	1% <i>m/V</i> in 0.1M HCl; watervrij
Specific absorbance	270 - 290	289		353 nm
Lightabsorbing impurities	E430 <0,50	0,17		Anhydrous
Lightabsorbing impurities	E490 <0,20	0,02		Anhydrous
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	0,1	%	
Impurity B	<=2,0	0,2	%	
Impurity C	<=2,0	1,1	%	
Total impurities D, E and F	<=2,0	0,3	%	
Heavy metals	<=50	Conform	ppm	
Water (Karl Fischer)	<=2,0	0,7	%	
Sulphated ash	<=0,5	0,0	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Oxytetracycline hydrochloride	95,0 - 102,0	99,3	% <i>m/m</i>	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Synergy Health.

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

21-05-13

Expiration: 03-2015 ✓

Conclusion: APPROVED

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