



Certificate of Analysis

Productname: Oxytetracyclini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-87196B
Batchnumber: 12A30-B05-272597
Reference code / No.: 2016 / Y1-1106142-3
Analysed according to: PH.EUR 7.3

FARMADENT d.o.o.	
Minarikova ul. 6	
2000 Maribor	
Prejel: FUJS DRAGO	
<i>Zu Pej</i>	
Datum prijema:	28.3.2012
Pregledač:	BAROLT Robert, mag. farm., spec.
<i>Barolt</i>	
Datum pregleda:	28.3.2013

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</i> /V
Specific optical rotation	-188 - -200	-193	°	1% <i>m</i> /V in 0.1M HCl; waternrij
Specific absorbance	270 - 290	286		353 nm
Lightabsorbing impurities	E430 <0,50	0,01		Anhydrous
Lightabsorbing impurities	E490 <0,20	0,03		Anhydrous
Related substances	Conform	Conform		HPLC
Impurity A	<=0,5	0,2	%	
Impurity B	<=2,0	0,6	%	
Impurity C	<=2,0	0,8	%	
Total impurities D, E and F	<=2,0	0,3	%	
Heavy metals	<=50	Conform	ppm	
Water (Karl Fischer)	<=2,0	1,2	%	
Sulphated ash	<=0,5	0,1	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Oxytetracycline hydrochloride	95,0 - 102,0	96,4	% <i>m</i> /m	Anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

27-08-12

Expiration: 06-2015

Conclusion: APPROVED

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