

CERTIFICATE OF ANALYSIS

Product : CHLORTETRACYCLINE HYDROCHLORIDE

Product number : C0116
Batch number : 013927
Date of analysis : 29-02-2016
Expiry date : 31-10-2019

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

Appearance Solubility	SPECIFICATION yellow powder slightly soluble in water and alcohol, soluble in solutions of alkali hydroxides and carbonates	RESULT complies complies	UNITS	REMARKS
Identity:				
- C (chloride)	conform	complies		
- D (HPLC)	conform	complies		
рН	2.3 - 3.3	2.6		1% in H ₂ O
Specific optical rotation	-235 – -250	-243	0	0.25% in H ₂ O, anhydrous substance
Absorbance	≤ 0.40	0.10		E ₄₆₀ , 0.5% in H ₂ O
Related substances	conform	complies		HPLC
Heavy metals	≤ 50	complies	ppm	
Water	≤ 2.0	0.2	%	Karl Fischer
Sulphated ash	≤ 0.5	0.0	%	
Assay:				HPLC, anhydrous
- tetracycline HCl	≤ 6.0	4.5	%	substance
- chlortetracycline HCl	≥ 89.5	97.1	%	
- Σ chlortetracycline HCl and tetracycline HCl	94.5 – 102.0	101.6	%	

This certificate of analysis is conform the results of the supplier.

Conclusion: approved

Released by:

drs. J. van der Eem, pharmacist.

Department of Quality Control Duchefa B.V.

Date: 31-07-2018

The buyer is responsible to test each batch to ensure the product is suitable for their specific purpose.

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