

**OXITETRACICLINA HCL (EUR. PH.) USO VETERINARIO**

PRODUCT CODE: 46433108	CAS Nº: 2058-46-0	ANALYSIS Nº: 263/24
MANUFACTURER BATCH: YT240302080	CERTIFICATE ID: 43.782	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 21/03/2024	
METAPH BATCH: 0161024	RETEST DATE: 20/03/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow, hygroscopic, crystalline powder	Yellow, hygroscopic, crystalline powder
Solubility	Freely soluble in water, sparingly soluble in ethanol (96 %). Solutions in water become turbid on standing, owing to the precipitation of oxytetracycline.	
Identification B	Complies	Complies
Identification C	Complies	Complies
Identification D	Complies	Complies
pH	2.3 - 2.9	2.6
Light-absorbing impurities		
Absorbance 430 nm	<= 0.50	0.15
Absorbance 490 nm	<= 0.20	0.03
Related substances		
Impurity C	<= 2.0 %	0.1 %
Impurity B	<= 1.0 %	0.7 %
Sum of impurities D, E and F	<= 1.0 %	0.1 %
Impurity A	<= 0.5 %	0.2 %
Impurity D	<= 0.2 %	0.1 %
Impurity E	<= 0.2 %	Not Detected
Any other impurity	<= 0.1 %	0.095 % (RT=16.88 min)
Total impurities	<= 3.5 %	1.2 %
Water	<= 2.0 %	1.9 %
Sulfated ash	<= 0.2 %	0.1 %
Assay	94.5 - 102.0 %	97.4 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Oxytetracycline Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

STORAGE

Analysis date: 05/11/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000503



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Keep the container tightly closed. Keep in a cool and well-ventilated place.

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