



TECHNICAL DATA SHEET

46433108-TDS-ENG-2024

OXITETRACICLINA HCL (EUR. PH.) USO VETERINARIO		
DESCRIPTION DCI: OXYTETRACYCLINE HYDROCHLORIDE		DESCRIPTION DOE: OXITETRACICLINA HIDROCLORURO
CAS Nº: 2058-46-0	EC Nº: 218-161-2	AEMPS CODE: 2081CH
MOL. WEIGHT: 496,90	MOL. FORMULA: C ₂₂ H ₂₄ N ₂ O ₉ ·HCl	ARTICLE CODE: 46433108

ATTRIBUTES	SHOULD BE
Appearance	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
Identification C	Complies
Identification D	Complies
pH	2.3 - 2.9
Light-absorbing impurities	
Absorbance 430 nm	<= 0.50
Absorbance 490 nm	<= 0.20
Related substances	
Impurity C	<= 2.0 %
Impurity B	<= 1.0 %
Sum of impurities D, E and F	<= 1.0 %
Impurity A	<= 0.5 %
Impurity D	<= 0.2 %
Impurity E	<= 0.2 %
Any other impurity	<= 0.1 %
Total impurities	<= 3.5 %
Water	<= 2.0 %
Sulfated ash	<= 0.2 %
Assay	94.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

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.

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.