METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1361-TDS-ENG-2021

OXITETRACICLINA HCL (PH.EUR)		
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: C22H24N2O9·HCl	ARTICLE CODE: 1361

ATTRIBUTES	SHOULD BE
Appearance	Yellow, crystalline powder, hygroscopic
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	
Absorvance 430 nm	=< 0.50
Absorvance 490 nm	=< 0.20
Related substances	
Impurity C	=< 2.0 %
Impurity B	=< 1.0 %
Impurity A	=< 0.5 %
Impurity D	=< 0.2 %
Impurity E	=< 0.2 %
Sum of impurities D, E and F	=< 1.0 %
Any other impurity	=< 0.1 %
Total of impurities	=< 3.5 %
Water	=< 2.0 %
Sulfated ash	=< 0.2 %
Assay	94.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 10.0

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.