



TECHNICAL DATA SHEET

0527-TDS-ENG-2024

DOXICICLINA HICLATO (EUR. PH.)		
DESCRIPTION DCI: DOXYCYCLINE HYCLATE		DESCRIPTION DOE: DOXICICLINA HICLATO
CAS N°: 24390-14-5	EC N°: 657-194-0	AEMPS CODE: 1395HE
MOL. WEIGHT: 512.90	MOL. FORMULA: C ₂₂ H ₂₄ N ₂ O ₈ HCl	ARTICLE CODE: 0527

ATTRIBUTES	SHOULD BE
Appearance	Yellow, hygroscopic, crystalline powder
Solubility	Freely soluble in water and in methanol, sparingly soluble in ethanol (96%). It dissolves in solutions of alkali hydroxides and carbonates
Identification A	Complies
Identification B	Complies
Identification C	Complies
pH	2.0 - 3.0
Absorbance	
490 nm	= < 0.07
Related substances	
Impurity A	= < 2.0 %
Impurity F	= < 1.2 %
Impurity B	= < 0.5 %
Impurity C	= < 0.2 %
Unspecified impurities	= < 0.10 %
Total impurities	= < 3.0 %
Ethanol	4.3 - 6.0 %
Water	1.4 - 2.8 %
Sulfated ash	= < 0.4 %
Bacterial endotoxines	< 1.14 IU/mg
Assay	95.0 - 102.0 %

COMPLIES WITH

European Pharmacopeia 11.0

STORAGE

Keep tightly closed, in a dry and cool place and protected from the light.

REMARKS

Doxycycline Hyclate 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.