



TECHNICAL DATA SHEET

1705-TDS-ENG-2023

MINOCICLINA CLORHIDRATO (EUR. PH.)		
DESCRIPTION DCI: MINOCYCLINE HYDROCHLORIDE		DESCRIPTION DOE: MINOCICLINA HIDROCLORURO
CAS Nº: 128420-71-3	EC Nº: 686-512-0	AEMPS CODE: 1971CH
MOL. WEIGHT: 529.97	MOL. FORMULA: C ₂₃ H ₂₈ CIN ₃ O ₇ ·2H ₂ O	ARTICLE CODE: 1705

ATTRIBUTES	SHOULD BE
Appearance	Yellow, hygroscopic, crystalline powder
Solubility	Sparingly soluble in water, slightly soluble in ethanol (96 %). It dissolves in solutions of alkali hydroxides and carbonates
Identification A	Complies
Identification C	Complies
Appearance of solution	Clear
pH	=< 0.23
Light-absorbing impurities	3.5 - 4.5
Absorbance 560 nm	=< 0.06
Related substances	
Impurity A	=< 1.2 %
Impurity B	=< 0.8 %
Impurity C	=< 0.6 %
Impurity E	=< 0.6 %
Impurity F	=< 0.5 %
Impurity G	=< 0.5 %
Impurity H	=< 0.3 %
Any other impurity	=< 0.15 %
Total impurities	=< 3.5 %
Water	5.0 - 8.0 %
Sulfated ash	=< 0.5 %
Assay	94.5 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

In an airtight container, protected from light.

REMARKS

Minocycline 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.



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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.