

DOXICICLINA HICLATO (EUR. PH.)

PRODUCT CODE: 0527	CAS Nº: 24390-14-5	ANALYSIS Nº: 041/24
MANUFACTURER BATCH: YD210401081	CERTIFICATE ID: 41.261	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 11/04/2021	
METAPH BATCH: 0280224	RETEST DATE: 10/04/2025	

ATTRIBUTES	SHOULD BE	IS
Appearance	Yellow, hygroscopic, crystalline powder	Yellow, hygroscopic, crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
pH	2.0 - 3.0	2.2
Absorbance		
490 nm	= < 0.07	0.02
Related substances		
Impurity A	= < 2.0 %	1.1 %
Impurity F	= < 1.2 %	0.9 %
Impurity B	= < 0.5 %	0.1 %
Impurity C	= < 0.2 %	< 0.05%
Unspecified impurities	= < 0.10 %	< 0.05%
Total impurities	= < 3.0 %	2.1 %
Ethanol	4.3 - 6.0 %	4.7 %
Water	1.4 - 2.8 %	2.2 %
Sulfated ash	= < 0.4 %	0.02 %
Assay	95.0 - 102.0 %	96.5 %

COMPLIES WITH

European Pharmacopeia 11.0

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.

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

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

Analysis date: 08/04/2024
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

Manufacturer: 40000503
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