

**CLINDAMICINA HCL (EUR. PH.)**

PRODUCT CODE: 0406	CAS Nº: 21462-39-5	ANALYSIS Nº: 002/24
MANUFACTURER BATCH: K-230506B	CERTIFICATE ID: 40.592	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 03/05/2023	
METAPH BATCH: 0020124	RETEST DATE: 03/05/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder, slightly hygroscopic.	White crystalline powder, slightly hygroscopic
Solubility	Very soluble in water, slightly soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification D	Complies	Complies
pH	3.0 - 5.0	4.3
Specific optical rotation	+135 / +150	+140
Related substances		
Impurity C	=< 4.0 %	0.9 %
Impurity B	=< 2.0 %	0.7 %
Any other impurity	=< 0.5 %	< 0.5 % (#)
Total impurities	=< 6.0 %	2.5 %
Water	3.0 - 6.0 %	5.0 %
Sulfated ash	=< 0.5 %	0.04 %
Assay	92.0 - 102.0 %	101.2 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Impurities detailed underneath:

RT (2.54 min) = 0.39 %

RT (2.83 min) = 0.14 %

RT (5.10 min) = 0.09 %

RT (6.03 min) = 0.21 %

Clindamycin Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

(*) Data adapted from the manufacturer's certificate of analysis.

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

Store in a cool, well-ventilated place.

Analysis date: 19/01/2024

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000283

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