

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

PRODUCT CODE: 0406	CAS Nº: 21462-39-5	ANALYSIS Nº: 214/24
MANUFACTURER BATCH: K-240335F	CERTIFICATE ID: 43.258	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 30/03/2024	
METAPH BATCH: 0080824	RETEST DATE: 30/03/2027	

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	4.1
Specific optical rotation	+135 / +150	+144
Related substances		
Impurity C	=< 4.0 %	0.5 %
Impurity B	=< 2.0 %	0.5 %
Any other impurity	=< 0.5 %	< 0.5 % (#)
Total impurities	=< 6.0 %	1.4 %
Water	3.0 - 6.0 %	4.2 %
Sulfated ash	=< 0.5 %	0.1 %
Assay	92.0 - 102.0 %	98.1 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Individual impurities detailed underneath:

RT (2.81 min) = 0.15 %

RT (5.19 min) = 0.14%

RT (6.07 min) = 0.12 %

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: 08/11/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000283