

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

PRODUCT CODE: 0406	CAS Nº: 21462-39-5	ANALYSIS Nº: 066/23
MANUFACTURER BATCH: K-230101F	CERTIFICATE ID: 37.721	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/01/2023	
METAPH BATCH: 0090323	RETEST DATE: 01/01/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white crystalline powder	White crystalline powder
Solubility	Very soluble in water, slightly soluble in ethanol (96 %)	Complies (*)
Identification A	Complies	Complies
Identification D	Complies	Complies
pH	3.0 - 5.0	3.4
Specific optical rotation	+135 / +150	+142
Related substances		
Impurity C	=< 4.0 %	0.66 %
Impurity B	=< 2.0 %	0.16 %
Any other impurity	=< 0.5 %	< 0.50 % (#)
Total impurities	=< 6.0 %	1.2 %
Water	3.0 - 6.0 %	4.1 %
Sulfated ash	=< 0.5 %	0.02 %
Assay	92.0 - 102.0 %	98.4 %
Residual solvents [In-house]		(*) (**)
Acetone	=< 5000 ppm	Not Detected
Ethanol	=< 5000 ppm	138 ppm
Chloroform	=< 60 ppm	Not Detected

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

(# ) Other impurities detailed underneath:

RT (2.601 min) = 0.16 %

RT (2.290 min) = 0.08 %

RT (6.635 min) = 0.13 %

Clindamycin Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

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

(\*\*) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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: 29/03/2023

Signature: Albert Sánchez López (QP)

Conclusion: Complies

Original certificate available upon request

Manufacturer: 40000283

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