



## TECHNICAL DATA SHEET

0406-TDS-ENG-2023

CLINDAMICINA HCL (PH.EUR)		
DESCRIPTION DCI: CLINDAMYCIN HYDROCHLORIDE		DESCRIPTION DOE: CLINDAMICINA HIDROCLORURO
CAS N°: 21462-39-5	EC N°: 244-398-6	AEMPS CODE: 616CH
MOL. WEIGHT: 461.44	MOL. FORMULA: C <sub>18</sub> H <sub>34</sub> Cl <sub>2</sub> N <sub>2</sub> O <sub>5</sub> S	ARTICLE CODE: 0406

ATTRIBUTES	SHOULD BE
Appearance	White or almost white crystalline powder
Solubility	Very soluble in water, slightly soluble in ethanol (96 %)
Identification A	Complies
Identification D	Complies
pH	3.0 - 5.0
Specific optical rotation	+135 / +150
Related substances	
Impurity C	= < 4.0 %
Impurity B	= < 2.0 %
Any other impurity	= < 0.5 %
Total impurities	= < 6.0 %
Water	3.0 - 6.0 %
Sulfated ash	= < 0.5 %
Assay	92.0 - 102.0 %
Residual solvents [In-house]	
Acetone	= < 5000 ppm
Ethanol	= < 5000 ppm
Chloroform	= < 60 ppm

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Store in a cool, well-ventilated place, away from heat, flames, sparks and other sources of ignition.

### REMARKS

Clindamycin 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.

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.