



TECHNICAL DATA SHEET

1205-TDS-ENG-2023

LINCOMICINA HCL		
DESCRIPTION DCI: LINCOMYCIN HYDROCHLORIDE		DESCRIPTION DOE: LINCOMICINA HIDROCLORURO
CAS Nº: 154-21-2	EC Nº: 615-424-7	AEMPS CODE: 1848CH
MOL. WEIGHT: 461.02	MOL. FORMULA: C ₁₈ H ₃₇ ClN ₂ O ₇ S	ARTICLE CODE: 1205

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Very soluble in water, slightly soluble in ethanol (96 %), very slightly soluble in acetone
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y6
pH	3.5 - 5.5
Specific optical rotation	+135° / +150°
Related substances	
Impurity A	=< 0.5 %
Sum of areas due to Imp. B	=< 0.5 %
Impurity C	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 2.0 %
Water	3.1 - 4.6 %
Sulfated ash	=< 0.5 %
Bacterial endotoxines	=< 0.50 IU/mg
Assay	
Lincomycin HCl + Lincomycin B HCl	96.0 - 102.0 %
Lincomycin B HCl	=< 5.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Keep the containers tightly closed. Store in a cool and well-ventilated place.

REMARKS

Lincomycin Hydrochloride is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

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.