



TECHNICAL DATA SHEET

009483-TDS-ENG-2021

AMOXICILINA TRIHIDRATO POLVO		
DESCRIPTION DCI: AMOXICILLIN TRIHYDRATE		DESCRIPTION DOE: AMOXICILINA TRIHIDRATO
CAS Nº: 61336-70-7	EC Nº: 933-899-1	AEMPS CODE: 108TC
MOL. WEIGHT: 419.50	MOL. FORMULA: C ₁₆ H ₁₉ N ₃ O ₅ S 3H ₂ O	ARTICLE CODE: 009483

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder
Solubility	Slightly soluble in water, very slightly soluble in ethanol (96 %), practically insoluble in fatty oils. It dissolves in dilute acids and dilute solutions of alkali hydroxides
Identification A	Complies
pH	3.5 - 5.5
Specific optical rotation	+290 / +315
Related substances	
Any impurity	= < 1 %
N,N-Dimethylaniline	= < 20 ppm
Water	11.5 - 14.5 %
Sulfated ash	= < 1.0 %
Assay	95.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

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

REMARKS

Amoxicillin Trihydrate 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.