

TECHNICAL DATA SHEET

0319-TDS-ENG-2026

ARTEMISININA (ARTEMISIA ANNUA)		
DESCRIPTION DCI: ARTESUNATE		DESCRIPTION DOE: ARTESUNATO
CAS Nº: 63968-64-9	EC Nº: 700-290-5	AEMPS CODE: 8285A
MOL. WEIGHT: 282.14	MOL. FORMULA: C ₁₅ H ₂₂ O ₅	ARTICLE CODE: 0319

ATTRIBUTES	SHOULD BE
Appearance	Colorless needle crystals
Taste	Bitter
Identification (1)	Complies
Identification (2)	Complies
Identification (3)	Complies
Identification (4)	Complies
Melting point	150 - 153 °C
Optical rotation	+75 / +78
Related substances	
Total impurities	=< 0.25 %
Loss on drying	=< 0.5 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %
Residual solvents [In-house]	
Ethanol	=< 5000 ppm
Methanol	=< 3000 ppm
Dimethyl Sulfoxide	=< 600 ppm
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Escherichia coli	Absence/1g
Candida Albicans	Absence/1g
Pseudomonas aeruginosa	Absence/1g
Staphylococcus aureus	Absence/1g
Salmonella	Absence/1g

COMPLIES WITH

Manufacturer specifications

STORAGE

Store in a tightly closed container. Store in cool, dry and well-ventilated area.

REMARKS

Artemisinin 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".

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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.

Properties

ARTEMISININE and its derivatives are a family of drugs that have the fastest action of all common medicines against malaria caused by falciparum. Treatments that contain derivatives of the ARTEMISININE are now the standard treatment worldwide for malaria. The main component of ARTEMISININE is isolated from the *Artemisia annua* plant, an herb described in traditional Chinese medicine.