

# **TECHNICAL DATA SHEET**

0319-TDS-ENG-2019

ARTEMISININE (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: C15H22O5		ARTICLE CODE: 0319	

ATTRIBUTES	SHOULD BE
------------	-----------

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

**Appearance** 

Methanol =< 5000 ppm

Microbiological control

TAMC = < 1000 CFU/gTYMC = < 100 CFU/gEscherichia coli Absence/1g

# COMPLIES WITH

Manufacturer specifications

#### STORAGE

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

## **REMARKS**

Artemisinine is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline.

 $Certificates \ of \ residual \ solvents, \ allergens, \ non-GMO \ and \ BSE-TSE \ are \ available \ upon \ request.$ 

# **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.