



## TECHNICAL DATA SHEET

0199-TDS-ENG-2024

ATROPINA SULFATO (EUR. PH.)		
DESCRIPTION DCI: ATROPINE SULFATE		DESCRIPTION DOE: ATROPINA SULFATO
CAS Nº: 5908-99-6	EC Nº: 200-235-0	AEMPS CODE: 118SU
MOL. WEIGHT: 694.84	MOL. FORMULA: (C17H23NO3)2·H2SO4·H	ARTICLE CODE: 0199

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or colourless crystals
Solubility	Very soluble in water, freely soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Identification E	Complies
pH	4.5 - 6.2
Optical rotation	-0.50° / +0.05°
Related substances	
Impurity E	=< 0.3 %
Impurity H	=< 0.3 %
Impurity A	=< 0.2 %
Impurity B	=< 0.2 %
Impurity C	=< 0.2 %
Impurity D	=< 0.2 %
Impurity F	=< 0.2 %
Impurity G	=< 0.2 %
Unspecified impurities	=< 0.10 %
Total impurities	=< 0.5 %
Water	2.0 - 4.0 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

### COMPLIES WITH

European Pharmacopeia 11.0

### STORAGE

Store in a dry and well-ventilated place, away from sources of heat and direct sunlight.

### REMARKS

Atropine Sulfate 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.