



TECHNICAL DATA SHEET

1619-TDS-ENG-2021

SULFATIAZOL EP		
DESCRIPTION DCI: SULFATIAZOL		DESCRIPTION DOE: SULFATHIAZOLE
CAS N°: 72-14-0	EC N°: 200-771-5	AEMPS CODE: ---
MOL. WEIGHT: 255.32	MOL. FORMULA: C ₉ H ₉ N ₃ O ₂ S ₂	ARTICLE CODE: 1619

ATTRIBUTES	SHOULD BE
Appearance	White or slightly yellowish, crystalline powder
Solubility	Practically insoluble in water, slightly soluble in alcohol, practically insoluble in methylene chloride. It dissolves in dilute solutions of alkali hydroxides and in dilute mineral acids
Identification A	Complies
Identification B	Complies
Melting point	200 - 203 °C
Appearance of solution	Clear and not more intensely coloured than ref. sol. GY4
Acidity	= < 0.1 mL of 0.1 M NaOH
Related substances	
Individual impurities	= < 0.5 %
Loss on drying	= < 0.5 %
Sulfated ash	= < 0.1 %
Assay	99.0 - 101.0 %

COMPLIES WITH

European Pharmacopoeia 10.0

STORAGE

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

REMARKS

Sulfathiazole 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.