



TECHNICAL DATA SHEET

1605-TDS-ENG-2021

SULFADIAZINA PH.EUR.		
DESCRIPTION DCI: SULFADIAZINE		DESCRIPTION DOE: SULFADIAZINA
CAS N°: 68-35-9	EC N°: 200-685-8	AEMPS CODE: 986A
MOL. WEIGHT: 250.3	MOL. FORMULA: C ₁₀ H ₁₀ N ₄ O ₂ S	ARTICLE CODE: 1605

ATTRIBUTES	SHOULD BE
Appearance	White, yellowish-white or pinkish-white, crystalline powder or crystals
Solubility	Practically insoluble in water, slightly soluble in acetone, very slightly soluble in ethanol (96 %). It dissolves in solutions of alkali hydroxides and in dilute mineral acids
Identification A	Complies
Appearance of solution	Not more intensely coloured than ref. sol. Y5, BY5 or GY5
Acidity	=< 0.2 mL of 0.1 M NaOH
Related substances	
Impurity A	=< 0.3 %
Impurity B	=< 0.3 %
Impurity E	=< 0.2 %
Impurity F	=< 0.15 %
Any unspecified impurities	=< 0.05 %
Total 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 container tightly closed in a cool and dry place, and protected from light.

REMARKS

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

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.