



TECHNICAL DATA SHEET

002416-TDS-ENG-2024

FLUORESCEINA SODICA (EUR. PH.)		
DESCRIPTION DCI: FLUORESCEINA SODICA		DESCRIPTION DOE: FLUORESCEIN SODIUM
CAS Nº: 518-47-8	EC Nº: 208-253-0	AEMPS CODE: 1570SO
MOL. WEIGHT: 376,27	MOL. FORMULA: C20H10Na2O5	ARTICLE CODE: 002416

ATTRIBUTES	SHOULD BE
Appearance	Orange-red, fine powder, hygroscopic
Solubility	Freely soluble in water, soluble in ethanol (96 %), practically insoluble in hexane and in methylene chloride
Identification B	Complies
Identification D	Complies
Appearance of solution	Clear and orange-yellow with yellowish-green fluorescence
pH	7.0 - 9.0
Related substances	
Impurity A	<= 0,5 %
Impurity B	<= 0,5 %
Impurity C	<= 0,5 %
Unspecified impurities	<= 0,10 %
Sum of impurities other than A, B and C	<= 0,5 %
Chlorides	<= 0,25 %
Sulfates	<= 1,0 %
Zinc	Complies
Loss on drying	<= 10,0 %
Assay	95,0 - 103,0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

Fluorescein Sodium 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".

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.