



TECHNICAL DATA SHEET

002722-TDS-ENG-2024

NITROFURANTOINA (EUR. PH.)		
DESCRIPTION DCI: NITROFURANTOIN		DESCRIPTION DOE: NITROFURANTOINA
CAS N°: 67-20-9	EC N°: 200-646-5	AEMPS CODE: 86A
MOL. WEIGHT: 238,16	MOL. FORMULA: C8H6N4O5	ARTICLE CODE: 002722

ATTRIBUTES	SHOULD BE
Appearance	Yellow, crystalline powder or yellow crystals
Solubility	Very slightly soluble in water and in ethanol (96 %), soluble in dimethylformamide
Identification A	Complies
Identification B	Complies
Related substances	
Any impurity	=< 1.0 %
Loss on drying	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	98.0 - 102.0 %
Nitrofurazone	=< 0.01 %
Residual solvents	
Isopropyl alcohol	=< 5000 ppm
Isopropyl acetate	=< 5000 ppm
Acetic acid	=< 5000 ppm
Particle size	
40 mesh	100 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Store protected from light, at a temperature below 25 °C.

REMARKS

Nitrofurantoin 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.