

TECHNICAL DATA SHEET

2497-TDS-ENG-2026

FENITOINA SODICA (EUR. PH.)		
DESCRIPTION DCI: PHENYTOIN SODIUM		DESCRIPTION DOE: FENITOINA SODICA
CAS N°: 630-93-3	EC N°: 211-148-2	AEMPS CODE: 1334SO
MOL. WEIGHT: 274,25	MOL. FORMULA: C ₁₅ H ₁₁ N ₂ NaO ₂	ARTICLE CODE: 2497

<u>ATTRIBUTES</u>	<u>SHOULD BE</u>
Appearance	White or almost white, very hygroscopic, crystalline powder
Solubility	Complies
Identification A	Complies
Identification C	Complies
Appearance of solution	Clear and not more intensely coloured than reference solution BY6
Related substances	
Impurity E	<= 0.3 %
Impurity C	<= 0.2 %
Impurity D	<= 0.15 %
Unspecified impurities	<= 0.10 %
Total impurities	<= 0.5 %
Fenitoina libre	<= 1.0 mL of 0.1M NaOH
Water	<= 3.0 %
Assay	98.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 12.2

STORAGE

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

REMARKS

Phenytoin 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.