

**FENITOINA SODICA (EUR. PH.)**

PRODUCT CODE: 2497	CAS Nº: 630-93-3	ANALYSIS Nº: 194/24
MANUFACTURER BATCH: SC0100637A	CERTIFICATE ID: 43.023	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 01/05/2023	
METAPH BATCH: 0170724	EXPIRY DATE: 30/04/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or almost white, very hygroscopic, crystalline powder	White, very hygroscopic, crystalline powder
Solubility	Complies	Complies (*)
Identification A	Complies	Complies
Identification C	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than reference solution BY6	Complies
Related substances		
Impurity E	<= 0.3 %	0.05 %
Impurity C	<= 0.2 %	< 0.05 %
Impurity D	<= 0.15 %	< 0.05 %
Unspecified impurities	<= 0.10 %	< 0.05 %
Total impurities	<= 0.5 %	0.05 %
Water	<= 1.0 mL of 0.1M NaOH	0.1 mL of 0.1M NaOH
Assay	<= 3.0 %	2.8 %
	98.0 - 102.0 %	100.6 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Product fully analyzed within the EU, in compliances with the currents regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II

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".

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

Analysis date: 17/09/2024
Signature: Albert Sanchez Lopez (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40001107