METAPHARMACEUTICAL IND SL
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TECHNICAL DATA SHEET

1829-TDS-ENG-2023

LEVOTIROXINA SODICA (PH.EUR) T4		
DESCRIPTION DCI: LEVOTHYROXINE SODIUM	DESCRIPTION DOE: LEVOTIROXINA SODICA	
CAS Nº: 55-03-8	EC Nº: 200-221-4	AEMPS CODE: 1842SO
MOL. WEIGHT: 798.86	MOL. FORMULA: C15H10I4NNaO4·H2O	ARTICLE CODE: 1829

ATTRIBUTES	SHOULD BE
Appearance	Almost white or slightly brownish-yellow, fine, slightly hygroscopic, crystalline powder
Solubility	Very slightly soluble in water, slightly soluble in ethanol (96 %). It dissolves in dilute solution of alkali hydroxides
Identification A	Complies
Identification B	Complies
Appearance of solution	Not more intensely coloured than ref. sol. BY3
Specific optical rotation	+16 / +20
Related substances	
Impurity A	=< 1.0 %
Impurity F	=< 0.5 %
Impurity G	=< 0.3 %
Unspecified impurities	=< 0.2 %
Total impurities	=< 2.0 %
Water	6.0 - 12.0 %
Assay	97.0 - 102.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Protect from the effects of light and humidity. Keep container tightly closed, stored at 2 - 8 °C.

REMARKS

LEVOTHYROXINE SOIDUM 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.