METAPHARMACEUTICAL IND SL
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LEVOTIROXINA SODICA T4 (EUR. PH.)

PRODUCT CODE: 1829	CAS Nº: 55-03-8	ANALYSIS Nº: 06/23R	
MANUFACTURER BATCH:	4001/3/013/21	CERTIFICATE ID:	39.210
SUPPLIER BATCH:	----	MANUFACTURING DATE:	03/09/2021
METAPH BATCH:	0100222	RETEST DATE:	02/09/2025

ATTRIBUTES	SHOULD BE	IS
Appearance	Almost white or slightly brownish-yellow, fine, slightly hygroscopic, crystalline powder	Almost white, fine, slightly hygroscopic, crystalline powder
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Not more intensely coloured than ref. sol. BY3	Complies
Specific optical rotation	+16 / +20	+ 18
Related substances		
Impurity A	=< 1.0 %	< 0.05 %
Impurity F	=< 0.5 %	< 0.05 %
Impurity G	=< 0.3 %	< 0.05 %
Unspecified impurities	=< 0.2 %	0.1 %
Total impurities	=< 2.0 %	0.1 %
Water	6.0 - 12.0 %	9.4 %
Assay	97.0 - 102.0 %	99.9 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

Levothyroxine sodium 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.

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

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

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

Analysis date: 22/09/2023
Signature: Albert Sánchez López (QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000993
AZICO BIOPHORE INDIA PVT.LTD
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531021 Andhra Pradesh