

**LEVOTIROXINA SODICA T4 (EUR. PH.)**

PRODUCT CODE: 1829	CAS Nº: 55-03-8	ANALYSIS Nº: 151/24
MANUFACTURER BATCH: LTS20240105	CERTIFICATE ID: 42.423	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 26/01/2024	
METAPH BATCH: 0350524	EXPIRY DATE: 25/01/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Almost white or slightly brownish-yellow, fine, slightly hygroscopic, crystalline powder	Slightly brownish-yellow, 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	+17
Related substances		
Impurity A	=< 1.0 %	< 0.05 %
Impurity F	=< 0.5 %	0.2 %
Impurity G	=< 0.3 %	0.1 %
Unspecified impurities	=< 0.2 %	0.1 %
Total impurities	=< 2.0 %	0.4 %
Water	6.0 - 12.0 %	7.7 %
Assay	97.0 - 102.0 %	99.3 %

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.

All data controlled by Metapharmaceutical Industrial SL.

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

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

Analysis date: 10/07/2024
Signature: Cristina Borrell Olea (QA/QP)
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000349