

LIOTIRONINA SODICA T3 (EUR. PH.)

PRODUCT CODE: 002462	CAS Nº: 55-06-1	ANALYSIS Nº: 117/25
MANUFACTURER BATCH: LIS20250101	CERTIFICATE ID: 46.316	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 11/01/2025	
METAPH BATCH: 0030525	EXPIRY DATE: 10/01/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	White or slightly coloured, hygroscopic powder	Slightly coloured, hygroscopic powder
Identification A	Complies	Complies
Identification C	Complies	Complies
Identification E	Complies	Complies
Specific optical rotation	+18.0 / +22.0	+19.9
Related substances		
Impurity A	=< 1.0 %	0.6 %
Impurity E	=< 0.5 %	0.3 %
Impurity B	=< 0.3 %	< 0.05 %
Impurity C	=< 0.3 %	0.2 %
Impurity D	=< 0.2 %	< 0.05 %
Unspecified impurities	=< 0.10 %	< 0.10 % (#)
Total impurities	=< 2.0 %	1.3 %
Chlorides	=< 2.0 %	0.1 %
Loss on drying	=< 4.0 %	0.5 %
Assay	95.0 - 102.0 %	97.5 %

COMPLIES WITH

European Pharmacopoeia 11.0

REMARKS

(#) Unspecified impurities detailed underneath:

RT (6.03 min) = 0.06 %

RT (13.56 min) = 0.08 %

RT (30.09 min) = 0.09 %

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

Liothyronine 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".

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

Keep the container tightly closed. Store between 2 - 8 °C, protected from light.

Analysis date: 04/09/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies
 Original certificate available upon request

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