

**LIOTIRONINA SODICA T3 (EUR. PH.)**

PRODUCT CODE: 002462	CAS Nº: 55-06-1	ANALYSIS Nº: 150/24
MANUFACTURER BATCH: LIS20240102	CERTIFICATE ID: 42.422	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 13/01/2024	
METAPH BATCH: 0340524	EXPIRY DATE: 12/01/2027	

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	+20.0
Related substances		
Impurity A	=< 1.0 %	0.08 %
Impurity E	=< 0.5 %	0.47 %
Impurity B	=< 0.3 %	Not detected
Impurity C	=< 0.3 %	Not detected
Impurity D	=< 0.2 %	Not detected
Unspecified impurities	=< 0.10 %	< 0.10 %
Total impurities	=< 2.0 %	0.74 %
Chlorides	=< 2.0 %	1.7 %
Loss on drying	=< 4.0 %	1.6 %
Assay	95.0 - 102.0 %	99.9 %

**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.

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: 04/07/2024  
Signature: Albert Sanchez Lopez (QP)  
Conclusion: Complies  
Original certificate available upon request

Manufacturer: 40000349