



## TECHNICAL DATA SHEET

151410-TDS-ENG-2022

TIROIIDE POLVO FARMA - EU-GMP		
DESCRIPTION DCI: ---		DESCRIPTION DOE: ---
CAS N°: ---	EC N°: ---	AEMPS CODE: ---
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 151410

ATTRIBUTES	SHOULD BE
Appearance	Slightly yellow to brownish powder
Identification	Complies
Assay	
Levothyroxine	36.1 - 39.9 µg/grain (95.0 - 105.0 %)
Lithyronine	8.6 - 9.5 µg/grain (95.0 - 105.0 %)
Difference between T3 and T4	=< 6.0 %
Inorganic Iodide Limit	=< 0.01 %
Loss on drying	=< 6.0 %
Microbiological control	
TAMC	=< 1000 CFU/g
TYMC	=< 100 CFU/g
Salmonella	Absent
Escherichia coli	Absent
Fat	=< 4.0 %
Residual solvents	
Acetone	=< 5000 ppm

### COMPLIES WITH

USP 2022

### STORAGE

Store at room temperature away from sources of humidity and hot. Keep the product in the original container.

### REMARKS

Thyroid 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.

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

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.