



## TECHNICAL DATA SHEET

010441-TDS-ENG-2022

| TIROIDE SECA POLVO FARMA |                   |                      |
|--------------------------|-------------------|----------------------|
| DESCRIPTION DCI: ---     |                   | DESCRIPTION DOE: --- |
| CAS N°: ---              | EC N°: ---        | AEMPS CODE: ---      |
| MOL. WEIGHT: ---         | MOL. FORMULA: --- | ARTICLE CODE: 010441 |

| ATTRIBUTES              | SHOULD BE          |
|-------------------------|--------------------|
| Appearance              | Beige-brown powder |
| Identification          | Complies           |
| Assay                   |                    |
| Levothyroxine           |                    |
| Lithyronine             |                    |
| Inorganic Iodide Limit  | = < 0.01 %         |
| Loss on drying          | = < 6.0 %          |
| Microbiological control |                    |
| TAMC                    | = < 10000 UFC/g    |
| Salmonella              | Absence/10g        |
| E. Coli                 | Absence/1g         |
| Fat                     | = < 5.0 %          |
| Excipient               | Lactose            |
| Residual solvents       | Complies           |

### COMPLIES WITH

USP 2022

### STORAGE

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

### REMARKS

#### Origin

Tiroides Seca Polvo Farma is prepared starting from pig thyroid deriving from animals from European farms duly registered and slaughtered in an EC certified slaughterhouse and declared fit for human consumption after an official ante-mortem and post-mortem veterinary examination in compliance with Community legislation, Art.10, EC Reg. 1069/2009.

#### Product identification

Pig Thyroid is an "intermediate product" intended for the manufacture of medicines [EC 1069/2009], [EU 142/2011] y [EU 2015/9].

#### BSE/TSE

The thyroid gland, being of PIG, is excluded from the risk of TSE/BSE transmission such as established by the "Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medical products" - EMEA/410/01 Rev3-July 2011-chap.2 "Scope of the note for Guidance", note 8.

#### GMO (Reg.1829/1830/2003 CE and subsequent updates)

The thyroid gland is regularly harvested in genetically unmodified organisms.

#### Contaminants/residues of veterinary drugs (EU Reg. N.37/2010)

The product is compliant.

#### Heavy metal analysis (Reg. CE 629/2008)

The product is compliant.



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**Pesticides (Reg. CE 396/2005 and subsequent updates)**

The product is compliant.

**Dioxins/PCB (Reg. CE 1881/2006 and subsequent updates)**

The product is compliant.