

Certificate of Analysis

Product name: **Thyreoidum**
Batch number / Weight: **23I29-B04-232288 / 100 G**
Analysed according to: **USP**
Number of analysis / Inspection Code **23I29-B04 / INS-23-7586**
Reference Code / No.: **V01542 / 23/0006**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellowish to buff colored amorphous powder	Conform		
Identification	Conform	Conform		
Loss on drying	$\leq 6,0$	0,3	%	
Inorganic iodides	$\leq 0,01$	Conform	%	
Assay Levothyroxine (T4)	90,0-110,0	103,4	%	
Assay Liothyronine (T3)	90,0-110,0	94,4	%	
Total aerobic microbial count (TA)	$\leq 10^3$ CFU/g	<10	CFU / g	
Total yeasts and moulds (TYMC)	$\leq 10^2$ CFU/g	<10	CFU / g	
E. coli	Negative	Conform	/gram	
Salmonella	Negative	Conform	/10 gram	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab,CBMiA

Release:
 Dominika Sołtysik
 Qualified Person

29-10-2023

Expiration: 28-02-2025

Conclusion: APPROVED

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