

Certificate of Analysis

Product name: **Thyreoidum**

Batch number / Weight: **22A11-B01-216844 / 100 G**

Analysed according to: **USP/ EP(for Residual solvents)**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellowish to buff colored amorphous powder	Conform		
Identification	Conform	Conform		
Loss on drying	$\leq 6,0$	1,8	%	
Inorganic iodides	$\leq 0,01$	Conform	%	
Assay Levothyroxine (T4)	90,0-110,0	105,2	%	
Assay Liothyronine (T3)	90,0-110,0	99,6	%	
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
Residual solvents				
Acetone	not more than 3000 ppm	<5000	ppm	

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

28-04-2022

Expiration: 30-11-2023

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.