

Certificate of Analysis

Product name: Levothyroxinum natricum
Batch number / Weight: 24F28-B36-006395 / 1 g
Producer / Producer Batch Number: Peptido GmbH / 21713
Analyzed according to: Ph. Eur. 11.6
Number of Analysis / Certificate no.: 24F28-B36 / Q00011323

	Requirement	Result	Unit	Standard remark
Appearance	Almost white or slightly brownish-yellow, fine, slightly hygroscopic, crystalline powder	Conform		
Identification	A, B	Conform		
Appearance of solution	<=BY3	Conform		
Specific optical rotation	(+16)-(+20)	+17,0		
Related substances	Conform	Conform		
Impurity A	<=1,0	0,06	%	
Impurity F	<=0,5	0,07	%	
Impurity G	<=0,3	<0,05	%	
Unspecified impurities	<=0,2	<0,05	%	
Total impurities	<=2,0	0,13	%	
Water	6,0-12,0	9,9	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	97,0 - 102,0	100,32	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

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 FSNE LAB, QUERCUS

Release:

13-2-2025
 Ewelina Gadzinowska
 Qualified Person

Expiration: 14-4-2027

Conclusion: APPROVED

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