

## Certificate of Analysis

**Product name:** **Levothyroxinum natricum**  
**Batch number / Weight:** **21G12-B01-213970 / 100 MG**  
**Analysed according to:** **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white or slightly brownish-yellow, fine, slightly hygroscopic, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Appearance of solution	<=BY3	Conform		
Specific optical rotation	+16 - +20	+19		
Related substances	Conform	Conform		
Impurity A	<=1,0	0,18	%	
Impurity F	<=0,5	0,14	%	
Impurity G	<=0,3	<0,05	%	
Unspecified impurities	<=0,2	<0,05	%	
Total impurities	<=2,0	0,32	%	
Water (Karl Fischer)	6,0 - 12,0	9,81	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Levothyroxine sodium	97,0 - 102,0	98,5	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

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Qualified Person

08-12-2021

Expiration: 07-05-2023

Conclusion: APPROVED

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