Certificate of Analysis

Product name: **Levothyroxinum natricum**

Batch number / Weight: **23D29-B02-230429 / 100 MG**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23D29-B02 / INS-23-7973**

Reference Code / No.: **V01685 / 21580**

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	+18,0		
Related substances	Conform	Conform		
Impurity A	<=1,0	0,074	%	
Impurity F	<=0,5	0,088	%	
Impurity G	<=0,3	0,00	%	
Unspecified impurities	<=0,2	<0,05	%	
Total impurities	<=2,0	0,16	%	
Water (Karl Fischer)	6,0 - 12,0	9,9	%	
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	100,05	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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,Quercus

Release:
Dominika Sołtysik
Qualified Person

27-11-2023

Expiration: 15-02-2025

Conclusion: APPROVED

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

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