

Certificate of Analysis

Productname: **Levothyroxinum natricum**
Number of analysis/Inspection Code: 1 / KEUR-181779B
Batchnumber: **20B07-F01-369082**
Reference code / No.: 2668 / 21247
Analysed according to: **PH.EUR10.0**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white or slightly brownish-yellow, fine,crystalline po	Conform		
Appearance	zwak hygroscopisch, kristallijn poeder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification B	Conform	Conform		Sodium
Appearance of solution	<=BY3	Conform		2%m/V in acidified alcohol
Specific optical rotation	+16 - +20	+19		2%m/V in acidified alcohol; anhydrous
Related substances	Conform	Conform		HPLC
Impurity A	<=1,0	0,1	%	
Impurity F	<=0,5	0,1	%	
Impurity G	<=0,3	<0,05	%	
Unspecified impurities	<=0,2	0,1	%	
Total impurities	<=2,0	0,3	%	
Water (Karl Fischer)	6,0 - 12,0	9,9	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Levothyroxine sodium	97,0 - 102,0	101,4	%m/m	HPLC; anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

05/13/20

Expiration: 11-2021

Conclusion: APPROVED

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