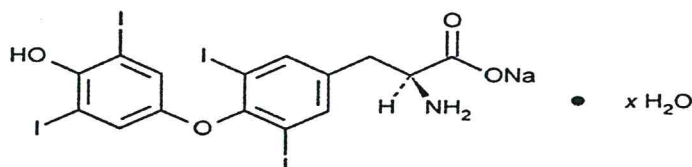


BATCH 21087

Certificate of Analysis

v06.0 - 06/2012

PRODUCT : LEVOTHYROXINE SODIUM
 (active substance)
INTERNAL CODE : L-T4 Na
MANUFACTURER : PEPTIDO GmbH
 Am Kraftwerk 6
 66450 Bexbach / GERMANY
CAS -NUMBER(S) : [25416-65-3]
BATCH SIZE <<kg>> : 42.0kg
PRODUCTION DATE : 03-2018
RETEST << MM/YYYY >> : 03-2020

C₁₅H₁₀I₄NNaO₄ * xH₂O 799,0 g/mol (anhydrous)

R1-CEP1998-048-Rev 04

PARAMETER	REQUIREMENT / ACCEPTANCE LIMIT	RESULT
Characters* -		
An almost white or slightly brownish-yellow, fine, slightly hygroscopic, crystalline powder.		
Very slightly soluble in water, slightly soluble in ethanol (96 per cent).		
It dissolves in dilute solutions of alkali hydroxides.		
Identification -		
Identification A (Ph. Eur. 2.2.24)	IR vs RS complies	complies
Identification B (Ph. Eur. 2.3.1)	white precipitation with K[Sb(OH)6]	complies
Optical rotation -		
Optical rotation (Ph. Eur. 2.2.7)	between + 16.0 and + 20.0°	+19.5°
Water		
Water (Ph. Eur. 2.5.32)	6.0 - 12.0%	10.0%
Impurities -		
Appearance of solution (Ph. Eur. 2.2.2 / II)	at most BY 3	BY6
Inorganic iodide	NMT 0.08%	complies
Residual solvents -		
Ethanol	NMT 1000ppm	14 ppm
Ethylamine	NMT 200ppm	<LOQ (= 3 ppm)
Related substances -		
(Ph. Eur. 2.2.29)		
Impurity A (Liothyronine)	NMT 1.0%	<0.05%
Impurity F	NMT 0.5%	0.07%
Impurity G	NMT 0.3%	<0.05%
unspecified impurities	NMT 0.2%	<0.05%
Total	NMT 2.0%	0.07%
Assay (Ph. Eur. 2.2.29) -		
Levothyroxine sodium	97.0 – 102.0%	100.2%
* not routinely performed		

SUGGESTED STORAGE AND RETEST -

In an airtight container, protected from light, at a temperature of 2°C to 8°C.

Retest 2 years after production date.

- ☒ The herewith analyzed substance is in accordance with specification and can be released
☐ The herewith analyzed substance is not in accordance with specification and must be rejected /
reworked / reprocessed

Bexbach 19. JULI 2018
M.Sailer; QC

checked & released by QA :

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20. JUNI 2018


Bernd Pannwitt