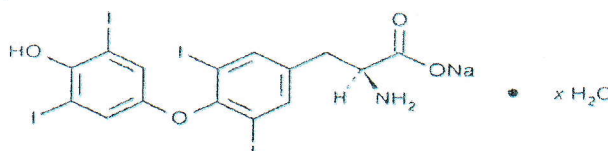


BATCH 2639

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>> : 40.0kg
 PRODUCTION DATE : 10-2012
 RETEST << MM/YYYY >> : 10-2014

C₁₅H₁₀I₂NNaO₄ · 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°	19.0°
Water		
Water (Ph. Eur. 2.5.32)	6.0 - 12.0%	9.8%
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	46 ppm
Ethylamine	NMT 200ppm	<LOQ (= 3ppm)
Related substances -		
(Ph. Eur. 2.2.29)		
Impurity A (Liothyronine)	NMT 1.0%	0.15%
Impurity F	NMT 0.5%	<0.05%
Impurity G	NMT 0.3%	<0.05%
unspecified impurities	NMT 0.2%	<0.05%
Total	NMT 2.0%	0.15%
Assay (Ph. Eur. 2.2.29) -		
Levothyroxine sodium	97.0 - 102.0%	100.8%
* 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
i.V. M.Sailer; QC

checked & released by QA :

07. APR 2011
S. K. Böhler
S. Genter

