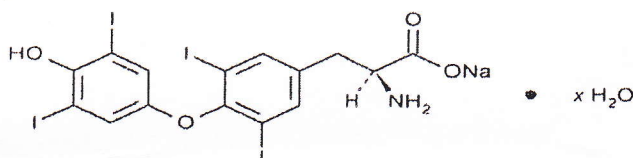


BATCH 2639

**Certificate of Analysis**

v06.0 - 06/2012

PRODUCT	:	LEVOTHYROXINE SODIUM
INTERNAL CODE	:	(active substance )
MANUFACTURER	:	L-T4 Na
	:	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

C<sub>15</sub>H<sub>10</sub>I<sub>4</sub>NNaO<sub>4</sub> \* xH<sub>2</sub>O 799,0 g/mol (anhydrous)

R1-CEP1998-048-Rev 04

PARAMETER	REQUIREMENT / ACCEPTANCE LIMIT	RESULT
<b>Characters* -</b>		
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.		
<b>Identification -</b>		
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) <sub>6</sub> ]	complies
<b>Optical rotation -</b>		
Optical rotation (Ph. Eur. 2.2.7)	between + 16.0 and + 20.0°	19.0°
<b>Water</b>		
Water (Ph. Eur. 2.5.32)	6.0 - 12.0%	9.8%
<b>Impurities -</b>		
Appearance of solution (Ph. Eur. 2.2.2 / II)	at most BY 3	BY6
Inorganic iodide	NMT 0.08%	complies
<b>Residual solvents -</b>		
Ethanol	NMT 1000ppm	46 ppm
Ethylamine	NMT 200ppm	<LOQ (= 3ppm)
<b>Related substances -</b>		
(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%
<b>Assay (Ph. Eur. 2.2.29) -</b>		
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 07. Jan 2013  
I.V. M.Sailer; QC

checked & released by QA :

07. JAN. 2013  
*S. Biehler*  
S. Biehler

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