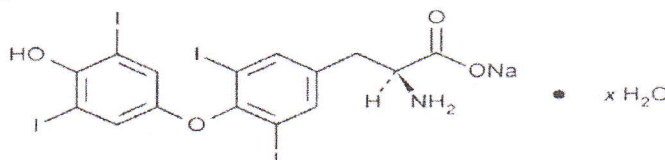


Certificate of Analysis

v06.0 - 06/2012

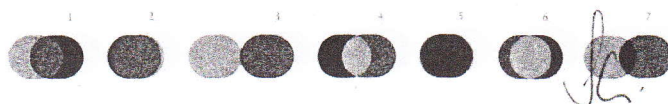
PRODUCT : LEVOTHYROXINE SODIUM
(active substance)
INTERNAL CODE : L-T4 Na
MANUFACTURER : PEPTIDO GmbH
Am Kraftwerk 6
66450 Bexbach / GERMANY
CAS -NUMBER(S) : [25416-65-3]
BATCH SIZE <<kg>> : 40.7kg
PRODUCTION DATE : 03-2015
RETEST << MM/YYYY >> : 03-2017

 $C_{15}H_{10}I_4NNaO_4 \cdot xH_2O$ 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°	+19.4°
Water		
Water (Ph. Eur. 2.5.32)	6.0 - 12.0%	9.9%
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	57 ppm
Ethylamine	NMT 200ppm	4 ppm
Related substances -		
(Ph. Eur. 2.2.29)		
Impurity A (Liothyronine)	NMT 1.0%	0.10%
Impurity F	NMT 0.5%	0.10%
Impurity G	NMT 0.3%	<0.05%
unspecified impurities	NMT 0.2%	<0.05%
Total	NMT 2.0%	0.20%
Assay (Ph. Eur. 2.2.29) -		
Levothyroxine sodium	97.0 - 102.0%	100.3%

* 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 02. Juni 2015
M.Sailer; QC

checked & released by QA :

Peptido GmbH
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02. JUNI 2015


B. Pannwitz

