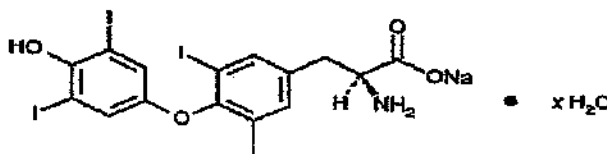


BATCH 2539

Certificate of Analysis

v04 - 07/2009

PRODUCT	:	LEVOTHYROXINE SODIUM
INTERNAL CODE	:	(active substance)
MANUFACTURER	:	L-T4 Na
	:	PEPTIDO GmbH
	:	Am Kraftwerk 6
CAS -NUMBER(S)	:	66450 Bexbach / GERMANY
	:	[25416-65-3] - USP
BATCH SIZE <<kg>>	:	[6106-07-06] - CEP-1998-048
PRODUCTION DATE	:	[55-03-8] - anhydrous
RETEST << MM/YYYY >>	:	40.0kg
	:	12-2010
	:	12-2012



CEP 1998-048 / valid version -

 $C_{15}H_{10}I_4NNaO_4 \cdot xH_2O$ 799,0 g/mol (anhydrous)**PARAMETER****REQUIREMENT / ACCEPTANCE LIMIT****RESULT****Characters* -**

An almost white or slightly brownish-yellow powder or a fine, crystalline powder, very slightly soluble in water, slightly soluble in alcohol, practically insoluble in ether. It dissolves in dilute solutions of alkali hydroxides.

Identification -

Identification A (Ph. Eur. 2.2.7)

complies with test for optical rotation

complies

Identification B (Ph. Eur. 2.2.24)

IR vs RS complies

complies

Identification E (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°

17.3°

Loss on drying -

Loss on drying (Ph. Eur. 2.2.32)

6.0 - 12.0%

9.8%

Impurities -

Appearance of solution

at most BY 3

BY6

(Ph. Eur. 2.2.2 / II)

Inorganic iodide

NMT 0.08%

complies

Residual solvents -

Ethanol

NMT 1000ppm

87 ppm

Ethylamine

NMT 200ppm

< LOQ (= 3 ppm)

Related substances -

(Ph. Eur. 2.2.29)

Liothyronine (T3; imp. A)

NMT 1.0%

0.06%

TRIMER (impurity F)

NMT 0.5%

0.07%

Any other detectable impurity

NMT 0.10%**

<0.05%

Sum of impurities other than A

NMT 1.0%

0.07%

Assay (Ph. Eur. 2.2.29) -**Levothyroxine sodium**

97.0 - 102.0%

99.5%

* not routinely performed

** other than those mentioned in the monograph



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.

ON CUSTOMERS REQUEST -

Morphology	REQUIREMENT / ACCEPTANCE LIMIT	RESULT
Particle size	at least 90.0% NMT 20µm	complies

- ☒ 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
Dr. Ralf Braun, QC

checked and released by QA: 02. Feb. 2011

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