No: 1901000040

PLIVA

CERTIFICATE OF ANALYSIS

Levothyroxine tablets 100 mcg	Code: L-TB-822/CE-05/2 Page: 1 of 2

Material code: 10024933
Batch No.: 607108
Specification: SDRA065350/4

Declaration: In house
Date of manufacture: 10.2018
Expiration date: 04.2020

TEST	RESULT	REQUIREMENT
DESCRIPTION	satisfactory	white, round biconvex tablets with score line on one side and marking 100 on the other side of the tablet
IDENTIFICATION (HPLC) Levothyroxine	satisfactory	the retention time of Levothyroxine peak in the Sample solution chromatogram corresponds to the retention time of Levothyroxine peak in the Standard solution chromatogram
IDENTIFICATION (UV) Levothyroxine	satisfactory	the UV spectrum of the Levothyroxine peak in the Sample solution and Levothyroxine peak in Standard solution obtained in the Assay test exhibit maxima at same wavelengths
ASSAY Each tablet should contain Levothyroxine sodium	100.3 %	95.0 – 105.0 % of the label claim
UNIFORMITY OF DOSAGE UNITS Content uniformity	satisfactory 104.3 % (102.6-105.8 %) AV=5.2	corresponds to the Ph. Eur. 2.9.40.
IMPURITIES Impurity A Impurity D Any unspecified impurity Total impurities	< 0.5 % < 0.5 % < 0.5 % < 0.5 %	not more than 1.0 % not more than 1.0 % not more than 1.0 % not more than 3.0 %

Date/Time: 10.12.2018 14:50:26
Approved by: Peters Ptiček Sanja, Qualified Person

This document has been electronically signed. UTC time

PLIVA

CERTIFICATE OF ANALYSIS

Levothyroxine tablets 100 mcg	Code: L-TB-822/CE-05/2 Page: 2 of 2

Material code: 10024933
Batch No.: 607108
Specification: SDRA065350/4

Declaration: In house
Date of manufacture: 10.2018
Expiration date: 04.2020

TEST	RESULT	REQUIREMENT
DISSOLUTION at 30 minutes	103 % (101-107 %) Stage:1	not less than 80 % (Q) of the label claim
LOSS ON DRYING	7.4 %	4.5 % - 9.5 %
MICROBIAL LIMITS [1] Total Aerobic Microbial Count Total Yeasts and Moulds Count *Escherichia coli*	 < 5 CFU/g < 5 CFU/g satisfactory	 not more than 10^3 CFU/g not more than 10^2 CFU/g absent
[1] first three production batches and every tenth batch thereafter, or at least one batch per year if less than 10 batches per year are manufacured		

Note: Placebo Batch No. used for analysis is 636058

Date/Time: 10.12.2018 14:50:26
Approved by: Peters Ptiček Sanja, Qualified Person

This document has been electronically signed, UTC time

PLIVA HRVATSKA d.o.o.

No. 10024933/607108

Certificate of Conformance

1. Name of product	:	LEVOTIROXINA SODICA
2. Importing Country	:	Chile
Quantity packed for importing country	:	20220,000 PC
3. Marketing Authorization Number	:	F-23648/17
4. Strength / Potency	:	100 mcg
5. Dosage form	:	Tablets
6. Package size and type Foil: Levotiroxina100mcgCIL-01 Box: 70057449 Leaflet: 70057448	:	Blister, 6*14
7. Batch number (finished product)	:	607108
Batch number (Bulk)	:	344108
Batch No. API	:	67902038
8. Date of manufacture Date of packaging:	: :	10.2018 11.2018
9. Expiry date	:	04.2020
10. Finished product storage conditions	:	up to +25°C
11. API Manufacturing site Name & Address	:	PEPTIDO GmbH,Am Kraftwerk 6, Germany-66450 Bexbach
Authorization number	:	/
Eudra GMP reference number or certificate of GMP Compliance	:	DE_SL_01_GMP_2016_0012
Bulk Manufacturing site Name Address Authorization number Eudra GMP reference number or certificate of GMP Compliance	: : : :	PLIVA HRVATSKA d.o.o. Prilaz baruna Filipovića 25, 10000 Zagreb, Croatia No UP/I-530-01/13-03/08 UP/I-530-10/16-03/04
Testing site Name Address Authorization number Eudra GMP reference number or certificate of GMP Compliance	: : : :	PLIVA HRVATSKA d.o.o. Prilaz baruna Filipovića 25, 10000 Zagreb, Croatia No UP/I-530-01/13-03/08 UP/I-530-10/16-03/04

Packaging site		
Name	:	PLIVA HRVATSKA d.o.o.
Address	:	Prilaz baruna Filipovića 25, 10000 Zagreb, Croatia
Authorization number	:	No UP/I-530-01/13-03/08
Eudra GMP reference number or certificate of GMP Compliance	:	UP/I-530-10/16-03/04
Batch release site		
Name	:	N/A
Address	:	N/A
Authorization number	:	N/A
Eudra GMP reference number or certificate of GMP Compliance	:	N/A

12. Result of analysis: CoA attached

13. Comments / remarks:

Major deviations: IR Number and Title:	☒ No	☐ Yes
Validation batch: Validation report Number and Title:	☒ No	☐ Yes

14. Certification statement:
"I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorization of the importing country or product specification file for investigational Medicinal Products. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP."

15. Name and position/title of person authorizing the batch release:

Qualified Person

PLIVA CROATIA Ltd.
Quality Zagreb
Qualified Person
Sanja Peters Ptiček

16. Signature of person authorizing the batch release: Peters Ptiček

17. Date of signature: 10.12.2018.