

No: 1901000040



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	< 0.5 %	not more than 1.0 %
Impurity D	< 0.5 %	not more than 1.0 %
Any unspecified impurity	< 0.5 %	not more than 1.0 %
Total impurities	< 0.5 %	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

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**CERTIFICATE OF ANALYSIS**

Levothyroxine tablets 100 mcg	Code: L-TB-822/CE-05/2 Page: 2 of 2
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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 <i>Escherichia coli</i>	< 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 manufactured		

Note: Placebo Batch No. used for analysis is 636058

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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 | : | Blister, 6*14 |
| Foil: | | Levotiroxina 100mcg CIL-01 |
| Box: | | 70057449 |
| Leaflet: | | 70057448 |
| 7. Batch number (finished product) | : | 607108 |
| Batch number (Bulk) | : | 344108 |
| Batch No. API | : | 67902038 |
| 8. Date of manufacture | : | 10.2018 |
| Date of packaging: | : | 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 | : | 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 |
| Testing 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 |

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: ☒ No ☐ Yes
IR Number and Title:

Validation batch: ☒ No ☐ Yes
Validation report Number and Title:

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:



17. Date of signature:

