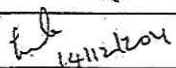
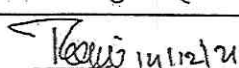
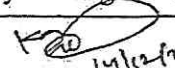


10/02/2022

CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM Ph.Eur		
Reference	Ph.Eur	Mfg. Date	03/09/2021
Batch No.	4001/3/013/21	Expiry Date	02/09/2024
Date of Analysis	13/09/2021	Dispatch Qty.	250.00 gm.
Name of the Customer	M/s. Caldic Denmark A/S.		

S. No	Test	Specification	Result
1.	Description	Almost white or slightly brownish-yellow, fine slightly hygroscopic, crystalline powder.	Slightly brownish-yellow powder.
2.	Solubility		
	a) In Water	Very slightly soluble in water	Complies
	b) In Ethanol	Slightly soluble in ethanol (96%)	Complies
	c) In alkali hydroxides	It dissolves in dilute solutions of alkali hydroxides.	Complies
3.	Identification By		
	A) IR	The IR absorption spectrum of sample should conform to that of standard.	Complies
	B) Test for sodium	Dense precipitate should be produced. Sodium compounds impart an intense yellow color to a non-luminous flame.	Complies
4.	Appearance of solution	Solution S not more intensely colored than reference solution BY ₃	Complies
5.	Specific optical rotation (on anhydrous basis) @ 25°C	Between +16 to +20	+18.0
6.	Water content (% w/w)	Between 6.0 to 12.0	9.20
7.	Related Substances By HPLC (% w/w)		
	a) Impurity-A	Not more than 1.0	BRL
	b) Impurity-F	Not more than 0.5	0.05
	c) Impurity-G	Not more than 0.3	BRL
	d) Unspecified impurity	Not more than 0.2	BRL
	e) Total Impurities	Not more than 2.0	0.05

	Prepared By	Checked By	Approved By
Name	S. Suresh	A. Venkat Raju	Baburao Koyyagura
Designation - Dept.	Chemist - QAD	Asst. Manager - QAD	Dy. Manager - QAD
Sign & Date	 14/12/2021	 14/12/2021	 14/12/2021

Format No: QAD/052-F01-00

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PLOT NO.: 40/A, J.N. PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM, A.P. INDIA

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CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM Ph.Eur		
Reference	Ph.Eur	Mfg. Date	03/09/2021
Batch No.	4001/3/013/21	Expiry Date	02/09/2024
Date of Analysis	13/09/2021	Dispatch Qty.	250.00 gm.
Name of the Customer	M/s. Caldic Denmark A/S.		

S. No	Test	Specification	Result
8.	Assay By HPLC (%w/w) (On anhydrous basis)	Not less than 97.0 and Not more than 102.0	99.5
9.	Residual solvents(by HPLC in ppm) Test: I		
	a) Acetic acid	Not more than 5000	Not detected
10.	Residual Solvents (By Headspace GC in ppm) Test: II		
	a) Methanol	Not more than 3000	BQL
	b) Acetone	Not more than 5000	BDL
	c) Isopropyl Alcohol	Not more than 5000	BDL
	d) Acetonitrile	Not more than 410	BDL
	e) Methyl isobutyl ketone	Not more than 4500	Not detected
	f) Toluene	Not more than 890	BDL
	g) Anisole	Not more than 5000	Not detected
11.	Residual Solvents (By Headspace GC in ppm) Test III		
	a) Triethyl amine	Not more than 320	Not detected

Chemical name of Impurities:

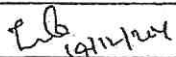
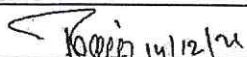
Impurity-A: (2S)-2-amino-3-[4-(4-hydroxy-3-iodophenoxy)-3,5-diiodophenyl]propanoic acid.
(Liothyronine)

Impurity-F: (2S)-2-amino-3-[4-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenoxy]-3,5-diiodophenyl] propanoic acid.

Impurity-G: Unknown structure.

Packaging and Storage Conditions: Finished product shall be packed in transparent LDPE bag with nitrogen purging, and tied with nylon strip followed by black LDPE bag along with silica gel desiccant and tied with nylon strip followed by triple laminated bag along with O-buster and hot seal and followed by HDPE container. Store at 2°C to 8°C, Preserve in tight container and protected from light.

Remarks: The material Complies comply with the above specification.

	Prepared By	Checked By	Approved By
Name	S. Suresh	A. Venkat Raju	Baburao Koyyagura
Designation - Dept.	Chemist - QAD	Asst. Manager - QAD	Dy. Manager - QAD
Sign & Date	 14/12/21	 14/12/21	 14/12/21

Format No: QAD/052-F01-00

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PLOT NO.: 40/A, J.N. PHARMA CITY, PARAWADA MANDAL, VISAKHAPATNAM, A.P. INDIA



Azico Biophore India Pvt. Ltd
425/3RT, Door No. 7-1-621/328
SR Nagar, Hyd-38, TS, INDIA
CIN NO.: U24233AP2008PTRC061809
☎ +91-40-2381 0385 / 23705066
☎ +91-40-2381 2709
✉ info@azicobiophore.com

LEVOTHYROXINE SODIUM Ph. Eur. (CAS No.: 25416-65-3)	
Batch No. : 4001/3/013/21	Drum No : 01 of 01
Manufacturing Date : 03/09/2021	Gross weight : 1.040 Kg.
Expiry Date : 02/09/2024	Tare weight : 0.790 Kg.
Mfg. license No : 03/VP/AP/2015/B/G	Net weight : 0.250 Kg.
NDC Number : 69575-4001-1	
Country of Origin : India	
Storage condition: Store in an airtight container, protected from light, at a temperature of 2-8°C.	
Caution : For manufacturing, processing, or repacking & "RX only"	
Manufactured by:	
 AZICO BIOPHORE INDIA PRIVATE LIMITED	
Manufacturing site Address: Plot No. 40/A, J.N. Pharma City, Parawada Mandal,, Visakhapatnam, Andhra Pradesh 531021, India (IND)	
Office address: 425/3RT, D. No: 7-1-621/328, Sanjeev Reddy Nagar, Hyderabad-500038, Telangana, INDIA. Telephone: 040-23810385, Fax : 040-23812709	
Format No.: QAD/027/4001-F02-02	

2.2 Label elements:

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP): GHS08

Signal word (CLP): Danger

Hazard statements (CLP): H373 - Causes damage to organs through prolonged or Repeated exposure

Precautionary statements (CLP): P260 - Do not breathe dust, vapours P314 -Get medical

Advice/attention if you feel unwell, P501 Dispose of

Contents/container



2.3 Other hazards: No additional information available



