AZICO BIOPHORE

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

CERTIFICATE OF ANALYSIS

Product Name	**LIOTHYRONINE SODIUM Ph.Eur.**		
Reference	**Ph. Eur.**	Mfg. Date	**15/09/2021**
Batch No.	**4010/2/004/21**	Retest Date	**14/09/2024**
Date of Analysis	**20/09/2021**	Dispatch Qty	---
Name of the Customer	----		

S. No.	Test Parameter	Specification	Results
1.	Description	White or slightly colored, hygroscopic powder.	Slightly colored hygroscopic powder.
2.	Solubility		
	a) Water	Practically insoluble in water	Complies
	b) Ethanol (96%)	Slightly soluble in Ethanol	Complies
	c) Alkali hydroxides	Dissolves in dilute solution of alkali hydroxides	Complies
3.	Identification by		
	A) UV and Visible Absorption Spectrophotometry (Dried substance)	Specific absorbance at absorption maximum between 63 to 69	68
	B) IR	The IR absorption spectrum of sample should conform to that of Liothyronine sodium Standard.	Complies
	C) Test for Iodine	Violet vapors should be evolved	Complies
	D) Test for Sodium	White precipitate should be produced	Complies
4.	Specific optical rotation(°) (On dried basis)	Between +18.0 to +22.0	+20.4
5.	Chloride Content (%) (On dried basis)	Not more than 2.0	0.30
6.	Loss on drying (%w/w)	Not more than 4.0	2.77
7.	Related substances by HPLC (%w/w)		
	a) Impurity-A	Not more than 1.0	0.09
	b) Impurity-B	Not more than 0.3	BRL
	c) Impurity-C	Not more than 0.3	BRL
	d) Impurity-D	Not more than 0.2	BRL
	e) Impurity-E	Not more than 0.5	0.12
	f) Unspecified impurities	Not more than 0.10	0.06
	g) Total impurities	Not more than 2.0	0.24
8.	Assay By HPLC (%w/w) (On dried basis)	Not less than 95.0 and Not more than 102.0	99.2

	Prepared By	Checked By	Approved By
Name	S. Suresh	E. Naga Brahmam	Baburao Koyyagura
Designation & Dept.	Chemist - QAD	Asst. Manager - QAD	Dy. Manager - QAD
Sign & Date	12/02/2022	12/02/2022	15/02/2022

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

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S. No.	Test Parameter	Specification	Results
9.	Residual solvents (By HPLC) Test I (ppm)		
	a) Acetic acid	Not more than 5000	Not Detected
10.	Residual Solvents (By Headspace GC) Test II (ppm)		
	a) Methanol	Not more than 3000	2261
	b) Ethanol	Not more than 5000	Not Detected
	c) Acetone	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) Test III (ppm)		
	a) Triethyl amine	Not more than 320	Not detected

Chemical Name of Impurities

Impurity-A: Levothyroxine.

Impurity-B: (2*S*)-2-amino-3-(4-hydroxy-3, 5-diiodophenyl) propanoic acid (diiodotyrosine)

Impurity-C: [4-(4-hydroxy-3-iodophenoxy)-3, 5-diiodophenyl] acetic acid (triiodothyroacetic acid)

Impurity-D: [4-(4-hydroxy-3, 5-diiodophenoxy)-3, 5-diiodophenyl]acetic acid (tetraiodothyroacetic acid)

Impurity-E: (2S)-2-amino-3-[4-(4-hydroxyphenoxy)-3, 5-diiodophenyl] propanoic acid (diiodotyronine)

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.

In an air tight container, protected from light, at a temperature between 2°C and 8°C.

Remarks: The Material Complies as per the above Specification.

	Prepared By	Checked By	Approved By
Name	S. Suresh	E. Naga Brahmam	Baburao Koyyagura
Designation & Dept.	Chemist - QAD	Asst. Manager - QAD	Dy. Manager - QAD
Sign & Date	12/02/2022	12/02/2022	12/02/2022

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