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

CERTIFICATE OF ANALYSIS

Product Name	**LIOTHYRONINE SODIUM USP**		
Reference	**USP / In house**	Mfg. Date	**16/03/2018**
Batch No.	**4010/2/001/18**	Retest Date	**15/03/2020**
Date of Analysis	**28/03/2018**	Sample Qty.	---
Name of the Customer	---		

S. No.	Test	Specification	Result
1.	Description	Light tan, odorless, crystalline powder	Light tan, odorless, crystalline powder
2.	Solubility		
	In alcohol	Slightly soluble in alcohol	Complies
	In water	Practically insoluble in water	Complies
	In organic solvents	Practically insoluble in most other organic solvents.	Complies
3.	Identification by		
	A) UV Absorptivity on dried basis (%)	Do not differ by more than 5.0	2.0
	B) Test for Iodine	Violet vapors should be evolved	Complies
	C) Test for Sodium	White precipitate should be produced	Complies
	D) By HPLC	Retention time of sample should conform to that of standard in assay method.	Complies
4.	Specific optical rotation(°) @ 25°C (On dried basis)	Between +18 to +22	+20.921°
5.	Loss on drying (%w/w)	Not more than 4.0	2.2
6.	Chloride Content (%)	Not more than 1.2	Less than 1.2
7.	Sodium Content (%)	NLT 2.9 and NMT 4.0	3.2
8.	Limit of Levothyroxine sodium (%)	Not more than 5.0	0.08
9.	Assay By HPLC (%w/w) (On dried basis)	Not less than 95.0 and Not more than 101.0	99.2
10.	Residual solvents (By HPLC) Test I (ppm)		
	a) Acetic acid	Not more than 5000	Not detected
11.	Residual Solvents (By Headspace GC) Test II (ppm)		
	a) Methanol	Not more than 3000	1407

	Prepared By	Checked By	Approved By
Name	Y. Mohan Rao	V. Udaya.V. Rao	S. Reddy Basha
Designation & Dept.	Sr. Chemist - QAD	Asst. Manager - QAD	Sr. Manager - QAD
Sign & Date	29/05/18	29/05/2018	29/05/2018

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CERTIFICATE OF ANALYSIS

Product Name	**LIOTHYRONINE SODIUM USP**		
Reference	**USP / In house**	Mfg. Date	**16/03/2018**
Batch No.	**4010/2/001/18**	Retest Date	**15/03/2020**
Date of Analysis	**28/03/2018**	Sample Qty.	---
Name of the Customer	---		

S. No.	Test	Specification	Result
	b) Ethanol	Not more than 5000	Not detected
	c) Acetone	Not more than 5000	BQL
	d) IPA	Not more than 5000	Not detected
	e) Acetonitrile	Not more than 410	BDL
	f) Methyl isobutyl ketone	Not more than 4500	Not detected
	g) Toluene	Not more than 890	Not detected
	h) Anisole	Not more than 5000	Not detected
12.	Residual Solvents (By Headspace GC) Test III (ppm)		
	a) Triethyl amine	Not more than 320	Not detected

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.

Preserve in tight containers, store at 2-8°C.

Chemical Name of Impurities:

Levothyroxine sodium: L-Tyrosine, O-(4-hydroxy-3, 5-diiodophenyl)-3, 5-diiodo-, monosodium salt, hydrate

Remarks: The Material Complies as per the above Specification.

	Prepared By	Checked By	Approved By
Name	Y. Mohan Rao	V. Udaya.V. Rao	S. Reddy Basha
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Sign & Date	29/05/18	29/05/2018	29/05/2018