

CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM Ph.Eur.		
Reference	Ph. Eur.	Mfg. Date	19/04/2019
Batch No.	4001/3/005/19	Expiry Date	18/04/2022
Date of Analysis	27/05/2019	Dispatch Qty	500.00 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	+18.48
6.	Water content (% w/w)	Between 6.0 to 12.0	8.40
7.	Related Substances By HPLC (% w/w)		
	a) Impurity-A	Not more than 1.0	BRL
	b) Impurity-F	Not more than 0.5	BRL
	c) Impurity-G	Not more than 0.3	BRL
	d) Unspecified impurity	Not more than 0.2	0.08
	e) Total Impurities	Not more than 2.0	0.25
8.	Assay By HPLC (% w/w) (On anhydrous basis)	Not less than 97.0 and Not more than 102.0	100.0

	Prepared By	Checked By	Approved By
Name	L. Dileep Kumar	E. Naga Brahmam	M.V.V. Satyanarayana
Designation & Dept.	Chemist - QAD	Executive - QAD	Manager - QAD
Sign & Date	L. Dileep 19/07/19	E. Naga Brahmam 19/07/19	M.V.V. Satyanarayana 19/07/2019

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S. No	Test	Specification	Result
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	BDL
	b) Acetone	Not more than 5000	BDL
	c) Isopropyl Alcohol	Not more than 5000	BQL
	d) Acetonitrile	Not more than 410	BQL
	e) Methyl isobutyl ketone	Not more than 4500	BQL
	f) Toluene	Not more than 890	3
	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.



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