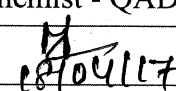
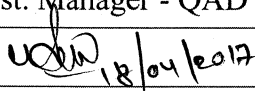



CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM Ph.Eur.		
Reference	Ph.Eur. / In house	Mfg. Date	14/01/2017
Batch No.	4001/3/001/17	Retest Date	13/07/2019
Date of Analysis	08/03/2017	Dispatch Qty	---
Name of the Customer	---		

S. No.	Test	Specification	Result
1.	Description	Almost white or slightly brownish-yellow, fine slightly hygroscopic, crystalline powder.	Slight 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	+19.30
6.	Water content (%w/w)	Between 6.0 to 12.0	9.5
7.	Related Substances By HPLC (% w/w)		
	Impurity-A	Not more than 1.0	0.01
	Impurity-F	Not more than 0.5	Not detected
	Impurity-G	Not more than 0.3	Not detected
	Unspecified impurity	Not more than 0.2	0.07
	Total Impurities	Not more than 2.0	0.17
8.	Assay By HPLC (%w/w) (On anhydrous basis)	Not less than 97.0 and Not more than 102.0	100.3

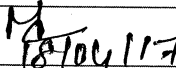
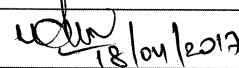
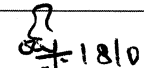
	Prepared By	Checked By	Approved By
Name	Y. Mohan Rao	V. Udaya.V. Rao	T. Ramesh
Designation & Dept.	Sr. Chemist - QAD	Asst. Manager - QAD	Dy. Manager- QAD
Sign & Date	 18/04/17	 18/04/2017	 18/04/2017

CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM Ph.Eur.		
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S. No.	Test	Specification	Result
9.	Residual solvents(By HPLC in ppm) Test I		
	Acetic acid	Not more than 5000	Not detected
10.	Residual Solvents (By Headspace GC in ppm) Test II		
	a) Methanol	Not more than 3000	Not detected
	b) Acetone	Not more than 5000	Not detected
	c) Isopropyl Alcohol	Not more than 5000	BDL
	d) Acetonitrile	Not more than 410	Not detected
	e) Methyl isobutyl ketone	Not more than 5000	15
	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		
	Triethyl amine	Not more than 320	Not detected
12.	Microbial Limit tests *		
	Total Aerobic microbial count (CFU/gm)	Not more than 100	Less than 70
	Total combined yeast and moulds count (CFU/gm)	Not more than 10	Less than 10
	a. <i>Escherichia coli</i>	Shall be Absent	Absent
	b. <i>Salmonella</i> species	Shall be Absent	Absent
	c. <i>Staphylococcus aureus</i>	Shall be Absent	Absent
	d. <i>Pseudomonas aeruginosa</i>	Shall be Absent	Absent
	e. Bile Tolerant Gram Negative Bacteria (<i>Enterobacteriaceae</i>)	Shall be Absent	Absent
	f. <i>Clostridia</i> species	Shall be Absent	Absent
	g. <i>Candida albicans</i>	Shall be Absent	Absent
13.	Bacterial Endotoxin test (EU/mg)	Not More Than 23	Less than 23

* Customer requirement

	Prepared By	Checked By	Approved By
Name	Y. Mohan Rao	V. Udaya.V. Rao	T. Ramesh
Designation & Dept.	Sr. Chemist - QAD	Asst. Manager - QAD	Dy. Manager- QAD
Sign & Date	 18/04/17	 18/04/2017	 18/04/2017

CERTIFICATE OF ANALYSIS

Product Name	LEVOTHYROXINE SODIUM Ph.Eur.		
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Batch No.	4001/3/001/17	Retest Date	13/07/2019
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Name of the Customer	---		

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 with clamp.

Store in an airtight container, protected from light, at a temperature of 2° to 8°C.

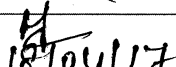
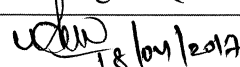
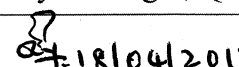
Chemical name of the impurities:

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.

Remarks: The Material Complies as per the above Specification.

	Prepared By	Checked By	Approved By
Name	Y. Mohan Rao	V. Udaya.V. Rao	T. Ramesh
Designation & Dept.	Sr. Chemist - QAD	Asst. Manager - QAD	Dy. Manager- QAD
Sign & Date	 18/04/17	 18/04/2017	 18/04/2017