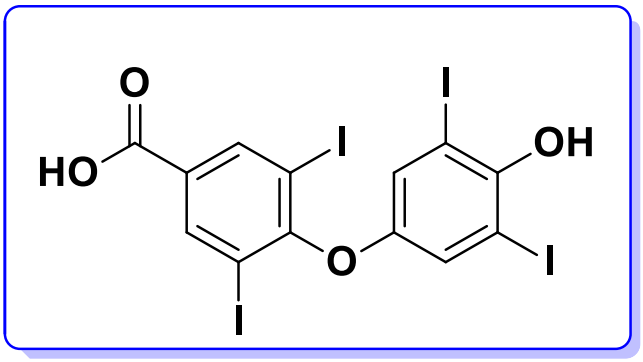
CERTIFICATE OF ANALYSIS

Analytical Reference substance

Levothyroxine Impurity H

34-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodobenzoic acid



Product Number No OLYLEVO.0H
CAS Number: N.A.
Lot Number: OLYLEVO0010.0H
Molecular Formula: C13H6I4O4
Molecular Weight: 734.0 g/mol

Long-term Storage: 2-8 ^{0}C
Appearance: Off White Solid
Melting Point: N.A.
Purity by HPLC: 95.54%

Manufacturing date: April-23-2018

Re-Test Date: April-23-2020

This certificate is valid for two years from the date of shipment
Provided the substance is stored under the recommended conditions.

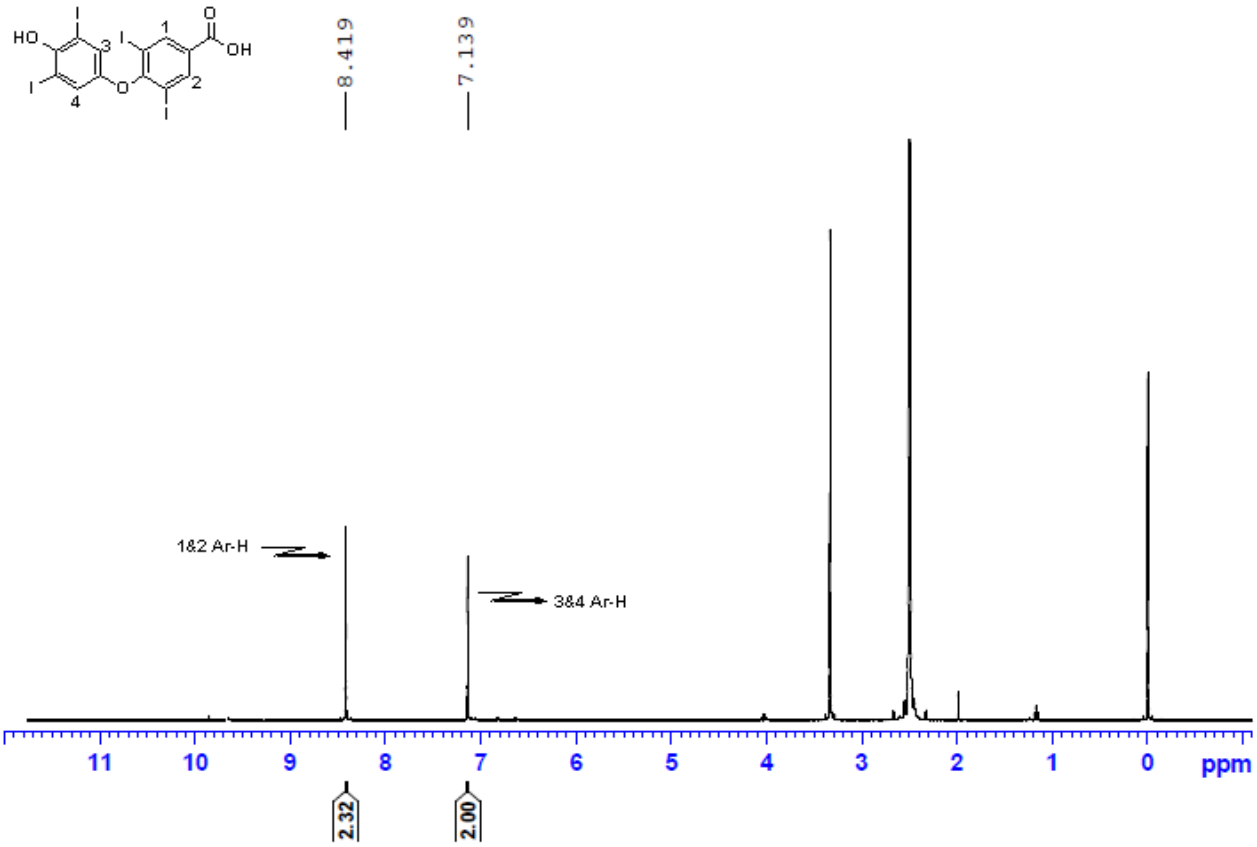
Additional information:
TLC Condition: (SIO2) plate Methanol / Methylene Chloride = 0.5 / 9.5, RF – 0.30 Single Spot, visualization in UV.

Corporate Office: Unit No F/10, 1st Floor Shubha Parvti Industrial Premises, Dombivali (East)
Kalyan-Thane-421201
Contact Company: www.Allmpus.com, Mo – +91-7506256625
For Further Enquiries: info@Allmpus.com

CERTIFICATE OF ANALYSIS

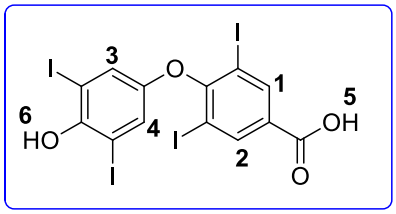
I. Identity
The identity of the reference substance was established by following analyses.

Ia. 1H-NMR Spectrum
Conditions: BRUKER 400 MHz, DMSO-d6
The structure is confirmed with the signals of the spectrum and their interpretation



Corporate Office: Unit No F/10, 1st Floor Shubha Parvti Industrial Premises, Dombivali (East)
Kalyan-Thane-421201
Contact Company: www.Allmpus.com, Mo – +91-7506256625
For Further Enquiries: info@Allmpus.com

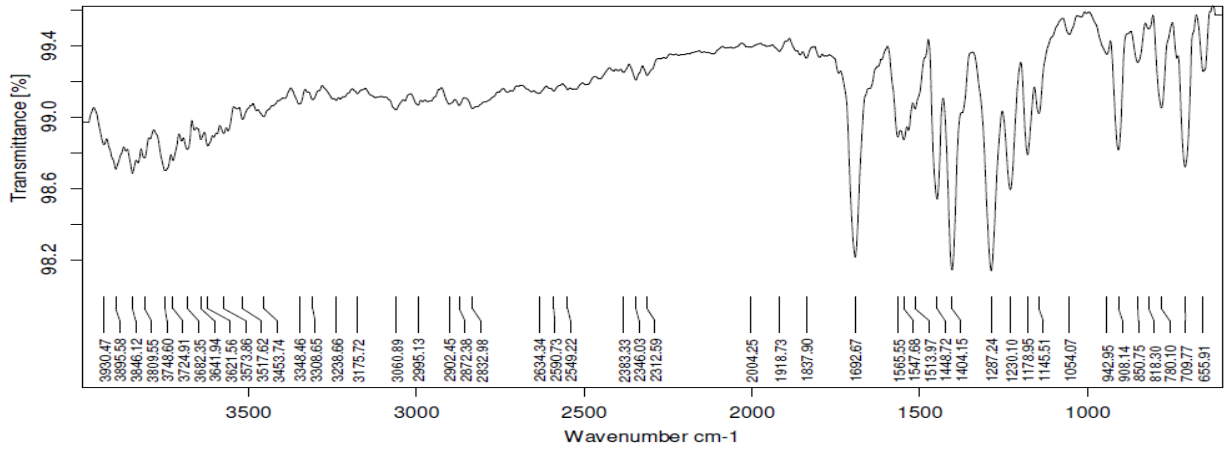
CERTIFICATE OF ANALYSIS



S. No.	Chemical Shift	Multiplicity	No Of proton	'J' Coupling	Assignment of proton
1 & 2	7.139	S	2H - Ar	-	2
3 & 4	8.419	S	2H - Ar	-	2
5	Acidic OH proton not observed - exchange with deuterated DMSO (d6)				1
6	phenolic OH proton not observed - exchange with deuterated DMSO (d6)				1
Total no of Proton			-	-	6
Remark			HMR Confirms The structure		

Ic. IR Spectrum

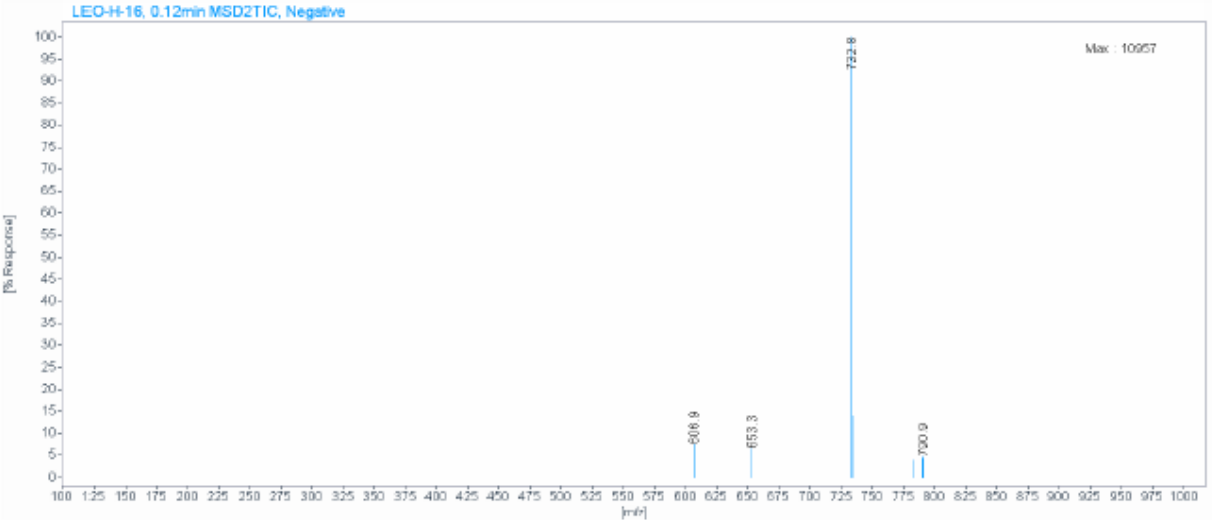
Method: Attenuated Total Reflection Fourier Transform Infrared (ATR-FTIR) Spectroscopy.
Instrument: BRUKER Model ALPHA.



IR Stretching	Observed Frequency	Reported Frequency
aromatic C-H stretching	2995.13	3030
Carboxylic C=O stretching	1692.67	1780 - 1710
aromatic C=C	1565.55-1513.97	1700 - 1500
C-O stretching	1287.24	1250-1050
Carboxylic OH	2549.22-2634.34	3000 - 2500
Phenolic OH	3175.72-3348.46	3550 – 3200
C-I	655.91	500

CERTIFICATE OF ANALYSIS

Ib. Mass Spectrum
Method: Agilent LC-, Model 1200 Infinity Series: Agilent MS, Model 6120



M/Z	Fragments
732.8	[M-1]
606.9	[C13H7I3O4]

The signal of the mass spectrum and their interpretation are consistent with the structural formula

Corporate Office: Unit No F/10, 1st Floor Shubha Parvti Industrial Premises, Dombivali (East)
Kalyan-Thane-421201
Contact Company: www.Allmpus.com, Mo – +91-7506256625
For Further Enquiries: info@Allmpus.com

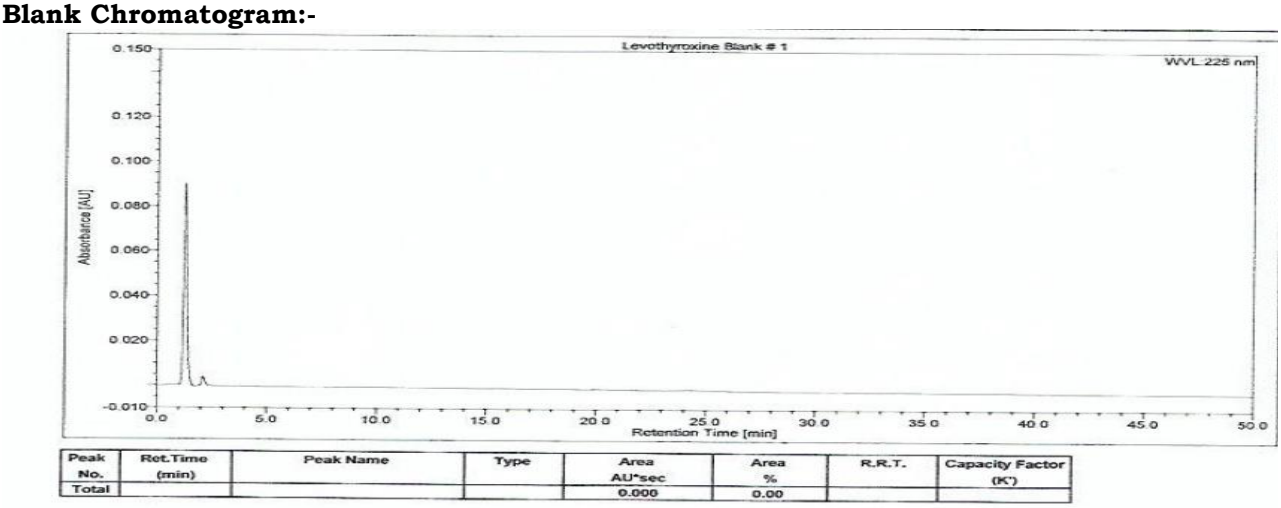
CERTIFICATE OF ANALYSIS

II. Purity
The purity of the reference substance was analyzed by SHIMADZU SCL-10AVP high performance liquid chromatography (HPLC).

HPLC Conditions:
Diluent: ACN: WATER (1:1)
Solution A: Dilute 5ml of phosphoric acid with Diluent to 100.0 ml
Mobile Phase: Dissolve1.0 gram of sodium 1-heptanesulfonate in 200ml water. Add 200ml of Acetonitrile, 400ml methanol, and 1.0ml of phosphoric acid dilute with water to 1L.

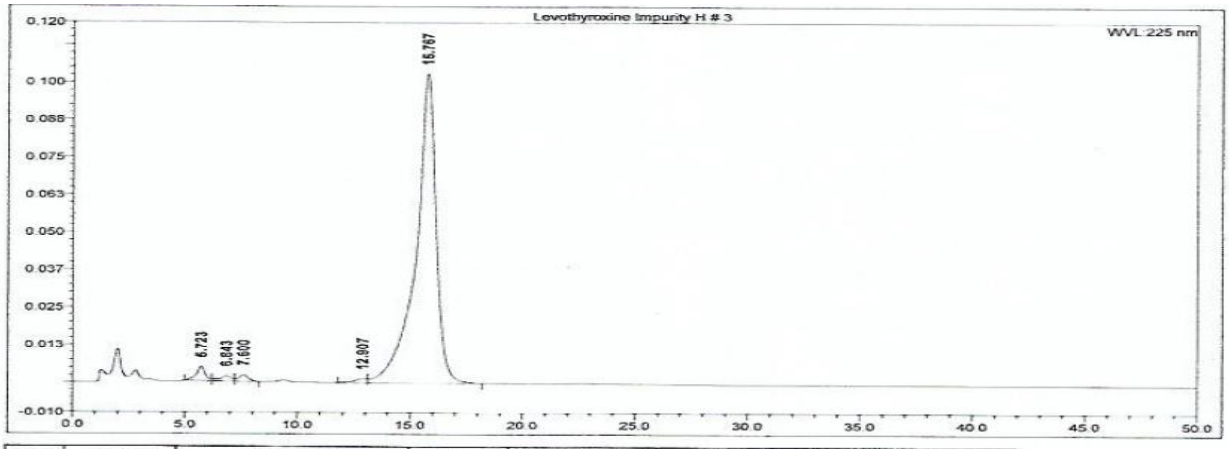
Column:	**Conditions:**	**Detector:**	**Injector:**
L7 packing (Luna) 5 µm, 150 x 4.6 mm	1.5 ml/min,	225nm/UV	Manual 15µl

Blank Chromatogram:-



Peak No.	Ret.Time (min)	Peak Name	Type	Area AU*sec	Area %	R.R.T.	Capacity Factor (K')
Total				0.000	0.00		

Lot Number: OLYLEVO0010.0H



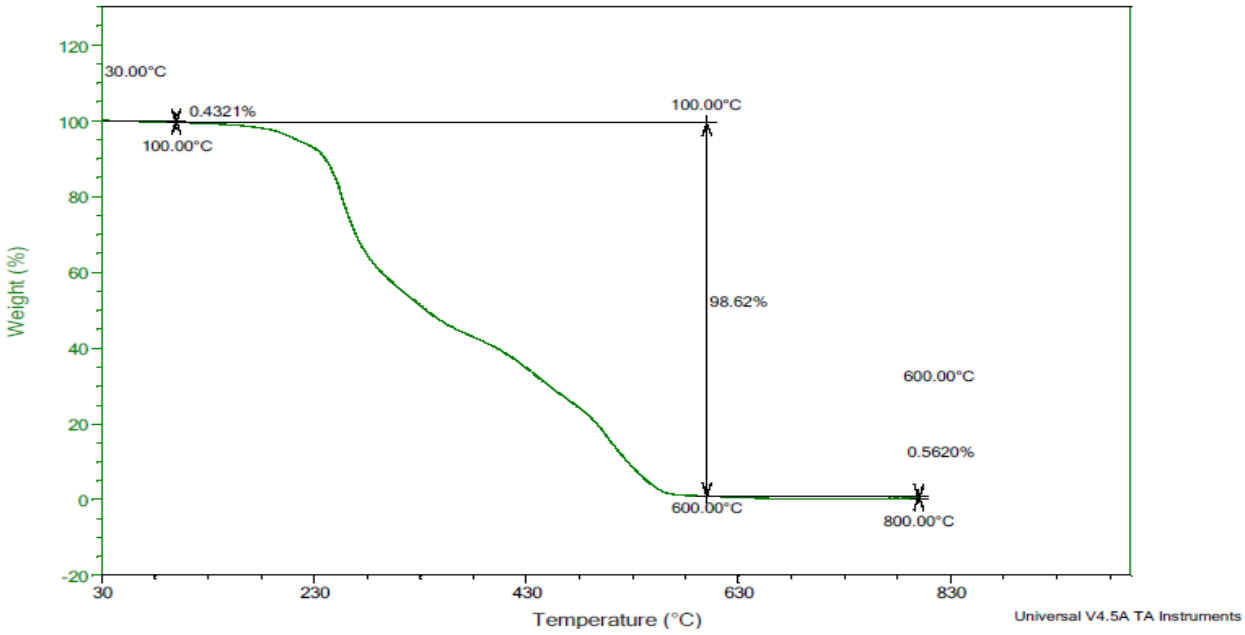
Peak No.	Ret.Time (min)	Peak Name	Type	Area AU*sec	Area %	R.R.T.	Capacity Factor (K')
1	5.723	n.a.	BM	0.127	1.90	n.a.	n.a.
2	6.843	n.a.	M	0.062	0.92	n.a.	n.a.
3	7.600	n.a.	MB	0.063	0.95	n.a.	n.a.
4	12.907	n.a.	BM	0.046	0.69	n.a.	n.a.
5	15.767	n.a.	MB	6.381	95.54	n.a.	n.a.
Total				6.680	100.00		

Corporate Office: Unit No F/10, 1st Floor Shubha Parvti Industrial Premises, Dombivali (East)
Kalyan-Thane-421201
Contact Company: www.Allmpus.com, Mo – +91-7506256625
For Further Enquiries: info@Allmpus.com

CERTIFICATE OF ANALYSIS

Results:
Purity: 95.54 %
Method: Levothyroxine USP (Procedure-1)

III. Water Content
Method: TGA Thermograms, The Percent of weight loss at 30-830^{0}C



IV. Residual Solvents
Method: 1H-NMR
No significant amounts of residual solvents were detected (< 0.05 %).

V. Potency
%Potency = [100 %-(Inorganic Impurities% + Water) × Chromatographic Purity%]/100
= [100 – (0.5620+0.4321) × 95.54]/100
= 95.41

VI. Final Result
Total impurities (HPLC) 4.46 %
Water Content: 0.4321%
Purity by HPLC: 95.54
Residual solvents: < 0.05 %
Potency: 95.41
Release Date: 2018-23-04

Reviewed By **Approved By**

Director of QA **Managing Director**

Corporate Office: Unit No F/10, 1st Floor Shubha Parvti Industrial Premises, Dombivali (East)
Kalyan-Thane-421201
Contact Company: www.Allmpus.com, Mo – +91-7506256625
For Further Enquiries: info@Allmpus.com