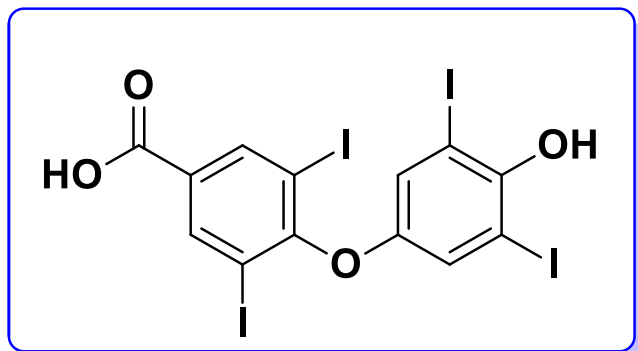


CERTIFICATE OF ANALYSIS

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 °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.

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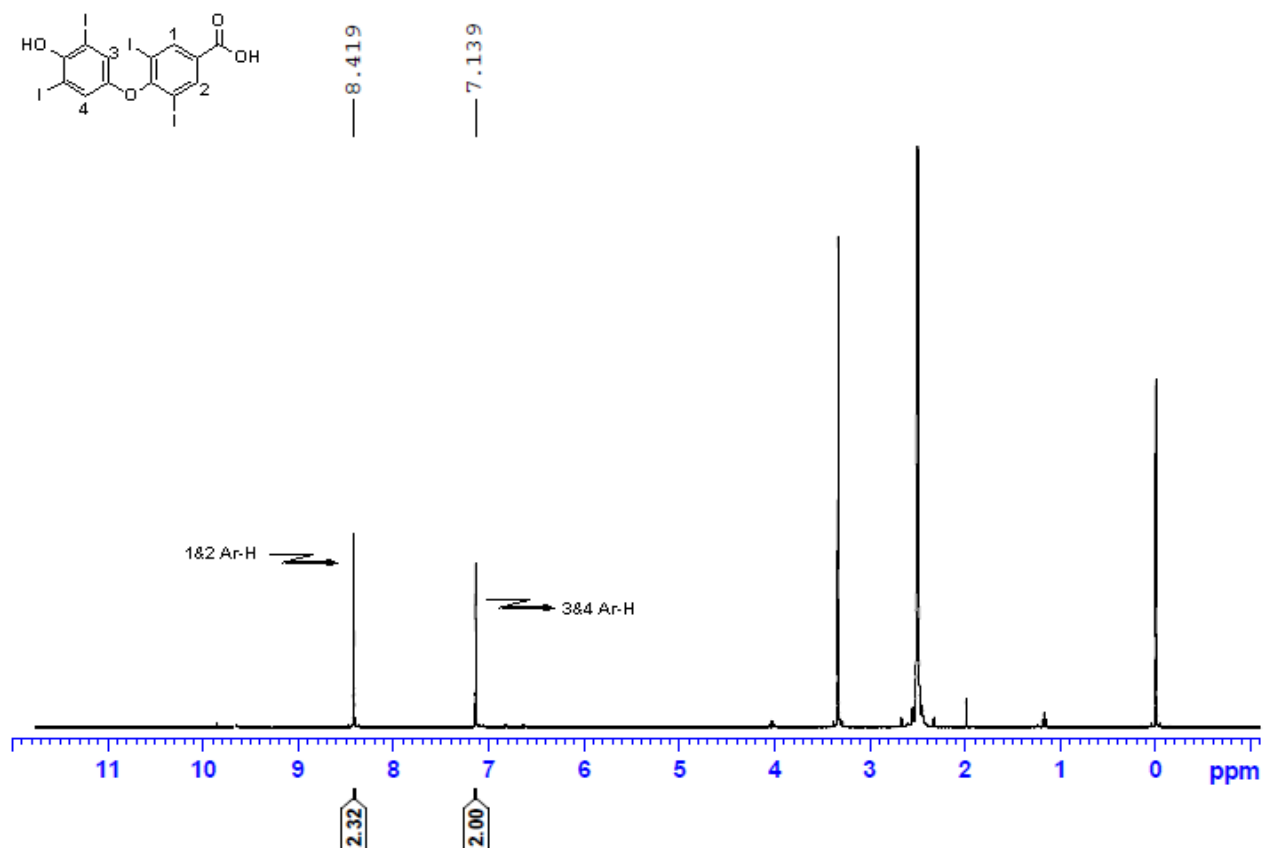
I. Identity

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

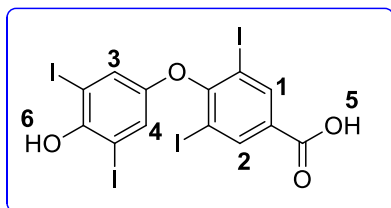


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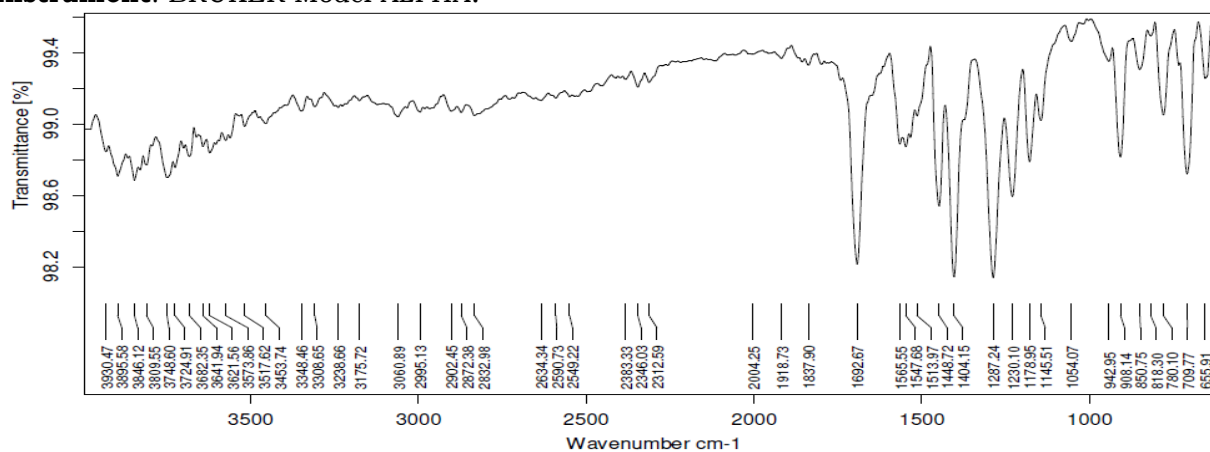


S. No.	Chemical Shift	Multiplicity	No Of proton	'J' Coupling	Assignment of proton
1 & 2	7.139	S	2H - Ar	-	2
3 & 4	8.419	S	2H - Ar	-	2
5	Acidic OH proton not observed - exchange with deuterated DMSO (d6)				1
6	phenolic OH proton not observed - exchange with deuterated DMSO (d6)				1
Total no of Proton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

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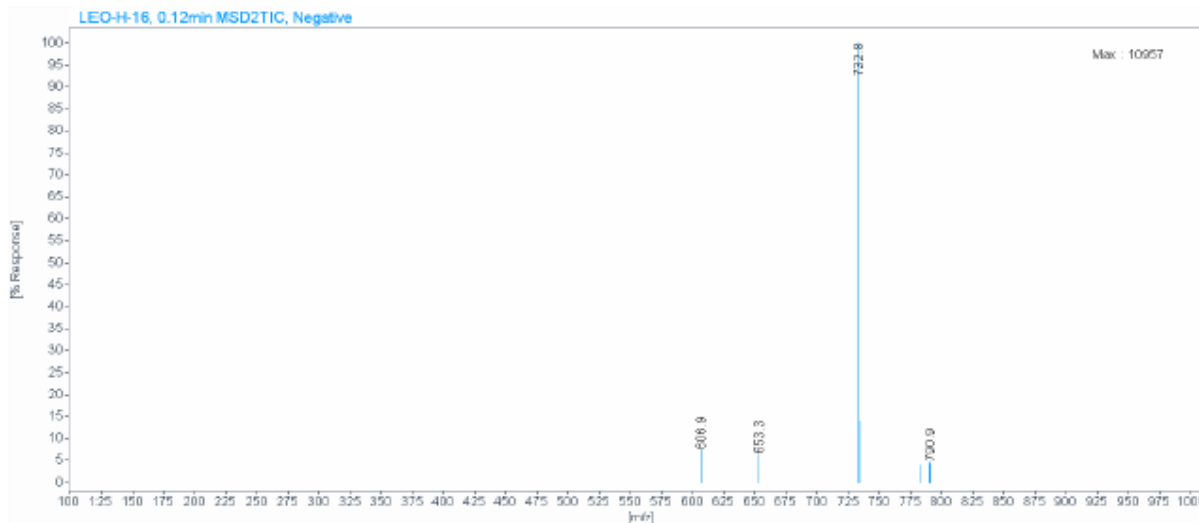
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CERTIFICATE OF ANALYSIS

Ib. Mass Spectrum

Method: Agilent LC-, Model 1200 Infinity Series: Agilent MS, Model 6120



M/Z	Fragments
732.8	[M-1]
606.9	[C ₁₃ H ₇ I ₃ O ₄]

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

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: Dissolve 1.0 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:

L7 packing (Luna)
5 µm, 150 x 4.6 mm

Conditions:

1.5 ml/min,

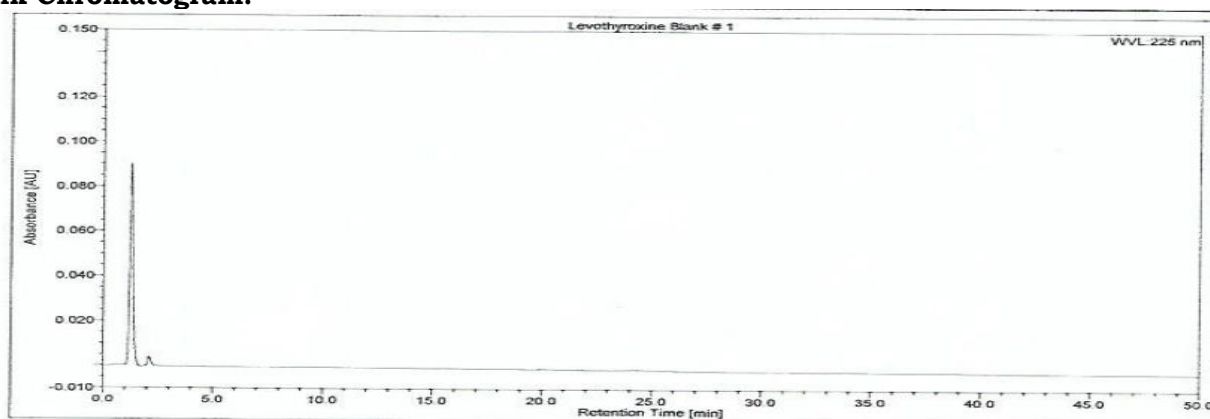
Detector:

225nm/UV

Injector:

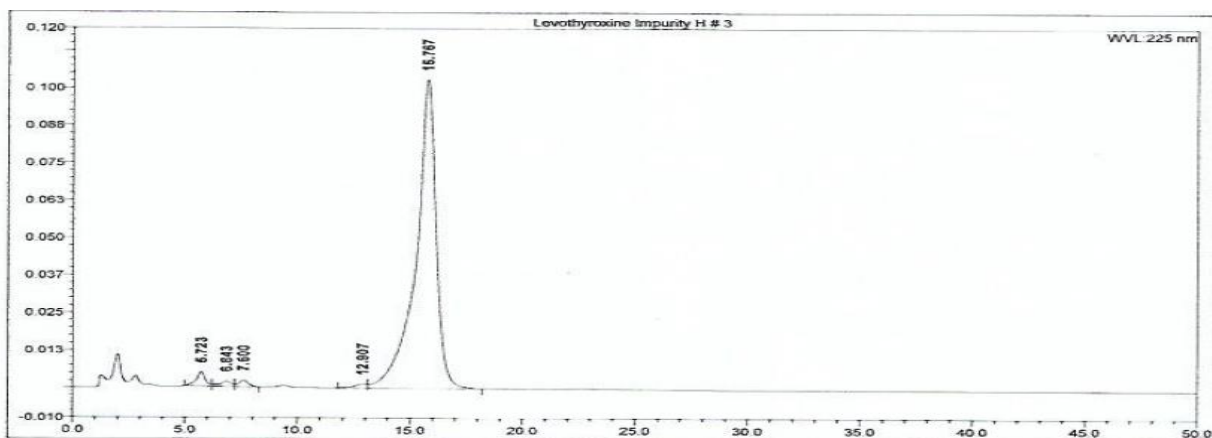
Manual
15µl

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.OH



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		

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CERTIFICATE OF ANALYSIS

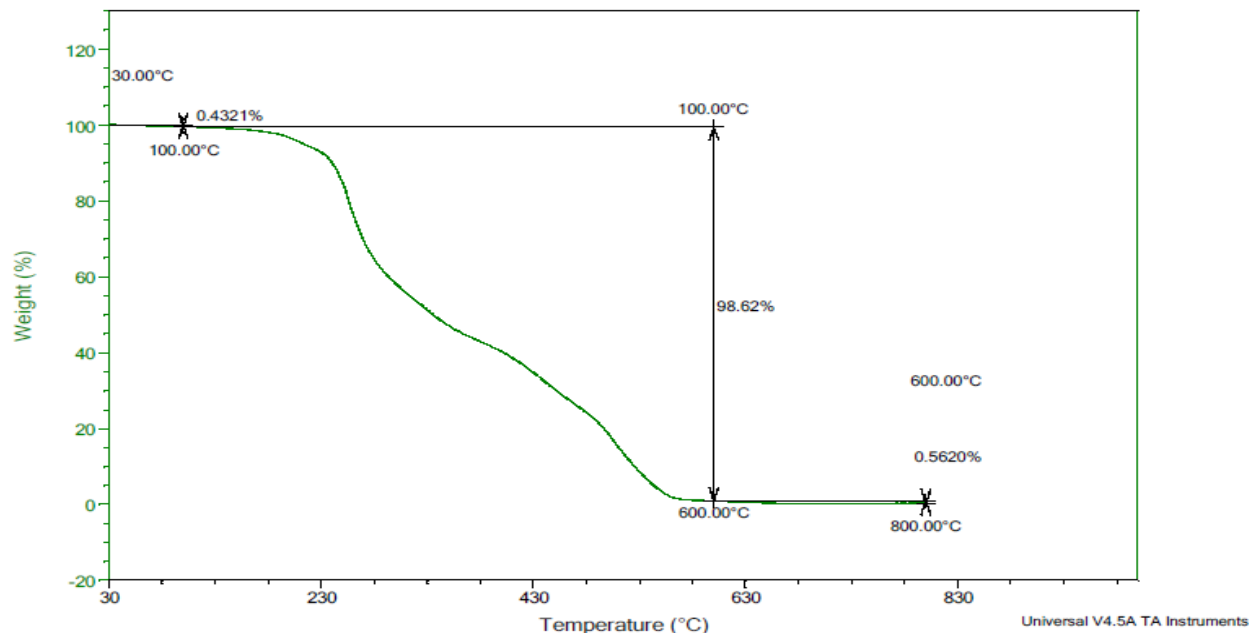
Results:

Purity: 95.54 %

Method: Levothyroxine USP (Procedure-1)

III. Water Content

Method: TGA Thermograms, The Percent of weight loss at 30-830°C



IV. Residual Solvents

Method: 1H-NMR

No significant amounts of residual solvents were detected (< 0.05 %).

V. Potency

$$\begin{aligned} \%Potency &= [100 \% - (\text{Inorganic Impurities}\% + \text{Water}) \times \text{Chromatographic Purity}\%] / 100 \\ &= [100 - (0.5620 + 0.4321) \times 95.54] / 100 \\ &= 95.41 \end{aligned}$$

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