

QUALITY CONTROL DEPARTMENT
[Certificate of Analysis Finished Product]
(FORM 39, RULE 150 E (F) THE DRUG AND
COSMETIC ACT, 1940 AND THE RULES THERE UNDER)

Product Name	: Healtroxin-50	AR Number	: FP-10-2024/1055
Generic Name	: Thyroxine Sodium Tablets IP 50mcg	Sample Quantity	: 100 Tablets
Batch No.	: KTB543B	Manufactured By	: Kureasia pharma Pvt. Ltd.
Batch Size	: 12.24 Lac	Manufactured For	: Healing Pharma India Pvt. Ltd.
Date of Received	: 27/10/2024	Manufacturing Date	: 09/2024
Date of Analysis	: 27/10/2024	Expiry Date	: 08/2026
Mfg. Lic. No.	: 20/UA/2023 & 18/UA/SC/P-2023	Date of Completion	: 02/11/2024
Reference Protocol No.	: KP/QC/FPS/033		

Sr. No	TEST PARAMETER	OBSERVATION	SPECIFICATIONS
1.	Description	White round, biconvex, uncoated tablets.	White round, biconvex, uncoated tablets.
2.	Identification <i>By High Performance Liquid Chromatography</i>	Meet the Requirement	In the assay, The principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.
3.	Dissolution Test <i>By High Performance Liquid Chromatography</i>	77.74% to 89.20%	Q. Not less than 70 per cent of the stated amount of $C_{15}H_{10}I_4NNaO_4$
4.	Liothyronine Sodium <i>By High Performance Liquid Chromatography</i>	0.56%	The area of any peak corresponds to Liothyronine is not more than 2.0 Per cent.
5.	Uniformity of content <i>By High Performance Liquid Chromatography</i>	101.22% to 103.53 %	85.00 % to 115.00 % of the labeled amount.
6.	Assay : <i>(By High Performance Liquid Chromatography)</i> Each uncoated tablet contains: Thyroxine Sodium IP Eq to Anhydrous Thyroxine Sodium 50mcg	50.87mcg	Shelf Life Limit: Not less than 45.00 mcg and Not more than 55.00 mcg (Not less than 90.00% and not more than 110.00 % of Label Claim) Release Limit: (Not less than 95.00% and not more than 105.00% of Label Claim) Not less than 47.5mcg and not more than 52.5 mcg.

ADDITIONAL TEST

7.	Average Weight	140.82mg	140.00 mg $\pm$ 7.5 %
8.	Uniformity of Weight	-2.57% to + 2.05 %	Not more than 2 of the individual weight deviate from the average weight by more than $\pm$ 7.5 % and none deviate by more than $\pm$ 15.0% of the average weight.
9.	Friability	0.10%	Not more than 1.00% w/w

Remark: Product complies / does not complies as per IP/BP/USP/HH specification.

Analyzed By :	Reviewed By :	Approved by
Sign/ Date  02/11/2024	Sign/Date  02/11/2024	Sign/Date  02/11/2024