

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)

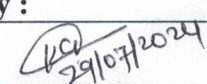
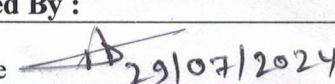
Product Name	: Healtroxin-125	AR Number	: FP-07-2024/0551
Generic Name	: Thyroxine Sodium Tablets IP 125mcg	Sample Quantity	: 100 Tablets
Batch No.	: KTB274B	Manufactured By	: Kureasia pharma Pvt. Ltd.
Batch Size	: 2.40 Lac	Manufactured For	: Healing Pharma India Pvt Ltd.
Date of Received	: 26/07/2024	Manufacturing Date	: 07/2024
Date of Analysis	: 26/07/2024	Expiry Date	: 06/2026
Mfg. Lic. No.	: 20/UA/2023 & 18/UA/SC/P-2023	Date of Completion	: 29/07/2024
Reference Protocol No.	: KP/QC/FPS/136		

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>	95.88% to 100.17%	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>	0.98%	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>	104.46% to 108.60 %	85.00 % to 115.00 % of the labeled amount.
6.	Assay : Each uncoated tablet contains: <i>(By High Performance Liquid Chromatography)</i> Thyroxine Sodium IP Eq to Anhydrous Thyroxine Sodium 125mcg	130.34mcg	Shelf Life Limit: Not less than 112.50 mcg and Not more than 137.50 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 118.75mcg and not more than 131.25 mcg.

ADDITIONAL TEST

7.	Average Weight	132.53 mg	130.00 mg $\pm$ 7.5 %
8.	Uniformity of Weight	-1.56% to + 1.22 %	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	0.20%	Not more than 1.00% w/w

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

Analyzed By :	Reviewed By :	Approved by
Sign/ Date 	Sign/Date 	Sign/Date 