

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-25	AR Number	: FP-11-2024/1099
Generic Name	: Thyroxine Sodium Tablets IP 25mcg	Sample Quantity	: 100 Tablets
Batch No.	: KTB676A	Manufactured By	: Kureasia pharma Pvt. Ltd.
Batch Size	: 12.24 Lac	Manufactured For	: Healing Pharma India Pvt. Ltd.
Date of Received	: 09/11/2024	Manufacturing Date	: 10/2024
Date of Analysis	: 09/11/2024	Expiry Date	: 09/2026
Mfg. Lic. No.	: 20/UA/2023 & 18/UA/SC/P-2023	Date of Completion	: 13/11/2024
Reference Protocol No.	: KP/QC/FPS/033		

Sr. No	TEST PARAMETER	OBSERVATION	SPECIFICATIONS
1.	Description	Orange colour , round, biconvex, uncoated tablets.	Orange colour , 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>	76.69% to 91.29%	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>	1.08%	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>	94.57% to 105.94 %	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 25mcg	25.17mcg	Shelf Life Limit: Not less than 22.50 mcg and Not more than 27.50 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 23.75mcg and not more than 26.25 mcg.

ADDITIONAL TEST

7.	Average Weight	135.97mg	130.00 mg $\pm$ 7.5 %
8.	Uniformity of Weight	-1.96% to + 1.71 %	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	0.24%	Not more than 1.00% w/w

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

Analyzed By :	Reviewed By :	Approved by
Sign/ Date <i>Ausop</i> 13/11/2024	Sign/Date <i>A</i> 13/11/2024	Sign/Date <i>Ah</i> 13/11/2024