Kureasia Pharma Pvt. Ltd, Haridwar

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-150	AR Number	: FP-08-2024/0668
Generic Name	: Thyroxine Sodium Tablets IP 150mcg	Sample Quantity	: 100 Tablets
Batch No.	: KTB351	Manufactured By	: Kureasia pharma Pvt. Ltd.
Batch Size	: 3.60 Lac	Manufactured For	: Healing Pharma India Pvt Ltd.
Date of Received	: 14/08/2024	Manufacturing Date	: 07/2024
Date of Analysis	: 14/08/2024	Expiry Date	: 06/2026
Mfg. Lic. No.	: 20/UA/2023 & 18/UA/SC/P-2023	Date of Completion	: 17/08/2024
Reference Protocol No.	: KP/QC/FPS/135		

Sr. No	TEST PARAMETER	OBSERVATION	SPECIFICATIONS
1.	**Description**	Light yellow colour, round, biconvex, uncoated tablets.	Light yellow colour, round, biconvex, uncoated tablets.
2.	**Identification** *By High Performance Liquid Chromatography*	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** *By High Performance Liquid Chromatography*	81.13% to 102.25%	Q. Not less than 70 per cent of the stated amount of $C_{15}H_{10}I_4NNaO_4$
4.	**Liothyronine Sodium** *By High Performance Liquid Chromatography*	Not detected	The area of any peak corresponds to Liothyronine is not more than 2.0 Per cent.
5.	**Uniformity of content** *By High Performance Liquid Chromatography*	92.62% to 95.98 %	85.00 % to 115.00 % of the labeled amount.
6.	**Assay :** **Each uncoated tablet contains:** *(By High Performance Liquid Chromatography)* Thyroxine Sodium IP Eq to Anhydrous Thyroxine Sodium 150mcg	150.47mcg	**Shelf Life Limit:** Not less than 135.00 mcg and Not more than 165.00 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 142.50mcg and not more than 157.50 mcg.
ADDITIONAL TEST			
7.	**Average Weight**	123.44 mg	120.00 mg ± 7.5 %
8.	**Uniformity of Weight**	-1.49% to + 1.74 %	Not more than 2 of the individual weight deviate from the average weight by more than ± 7.5 % and none deviate by more than ± 15.0% of the average weight.
9.	**Friability**	0.06%	Not more than 1.00% w/w

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

Analyzed By :	Reviewed By :	Approved by
Sign/ Date 17/08/2024	Sign/Date 17/08/2024	Sign/Date 17/08/2024