

astonea

ASTONEA LABS LTD.

Vill. Haripur, Teh. Raipur Rani, Distt. Panchkula -134204.

CERTIFICATE OF ANALYSIS

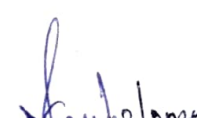
Product Name	Healtroxin- 50 Tablets		
Generic Name	Thyroxine Sodium Tablets IP 50 mcg		
Batch No.	TH24005A	A.R No.	AL/O/FGD2401654
Mfg. Date	Mar - 2024	Batch Size	1.20 Lac Tablets
Exp.Date	Feb - 2026	Sample Received on	21.03.2024
Sample Quantity	100 Tablets	Release Date	24.03.2024

S.No.	Tests	Specification	Results
1.	Description	A white colored round shape uncoated tablet, plain on both side	A white colored round shape uncoated tablet, plain on both side
2.	Identification	Should be Positive for Thyroxine Sodium	Complies
3.	Avg. weight of Tablet	120.0 mg $\pm$ 7.5 %	117.9 mg
4.	Uniformity of Weight	$\pm$ 7.5% of Average weight	-2.71 % to +3.90 %
5.	Uniformity of content	85 % to 115 % of stated amount of Thyroxine Sodium	95.8 % to 104.9 %
6.	Dissolution Test	NLT - 70.0 % (Q) of the stated amount of Thyroxine Sodium	82.9 %
7.	Friability	Not more than 1.0 %	0.08 %
8.	Liothyronine Sodium	Not more than 2.0 %	0.45 %
Assay			
9.	Each uncoated tablets contains: Thyroxine Sodium IP 50 mcg	NLT 90.0% and NMT 110.0% of the labeled amount of Thyroxine Sodium	98.46 %

Remarks: The above sample complies/ does not comply with prescribed standards of quality with respect to above tests as per IP/BP/USP /HIS Specification.

Analyzed by  24/03/24

Checked by  24/03/2024

Approved by  24/03/2024