

astonea

## ASTONEA LABS LTD.

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

CERTIFICATE OF ANALYSIS

|                 |                                     |                    |                 |
|-----------------|-------------------------------------|--------------------|-----------------|
| Product Name    | Healtroxin 12.5 Tablets             |                    |                 |
| Generic Name    | Thyroxin Sodium Tablets IP 12.5 mcg |                    |                 |
| Batch No.       | AOT24649A                           | A.R No.            | AL/O/FGD2401494 |
| Mfg. Date       | May - 2024                          | Batch Size         | 6.0 Lac Tablets |
| Exp.Date        | Apr - 2026                          | Sample Received on | 27.06.2024      |
| Sample quantity | 100 Tablets                         | Release Date       | 12.07.2024      |

| 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 %                                               | 118.3 mg                                                        |
| 4.    | Uniformity of Weight                                                          | $\pm$ 7.5% of Average weight                                       | -2.71 % to +2.35 %                                              |
| 5.    | Uniformity of content                                                         | 85 % to 115 % of stated amount of Thyroxine Sodium                 | 94.3 % to 105.0 %                                               |
| 6.    | Dissolution Test                                                              | NLT - 70.0 % of the stated amount of Thyroxine Sodium              | 77.8 %                                                          |
| 7.    | Friability                                                                    | Not more than 1.0 %                                                | 0.03 %                                                          |
| 8.    | Liothyronine Sodium                                                           | Not more than 2.0 %                                                | 0.16 %                                                          |
| Assay |                                                                               |                                                                    |                                                                 |
| 9.    | Each uncoated tablets contains:<br>Thyroxine Sodium(as anhydrous) IP 12.5 mcg | NLT 90.0% and NMT 110.0% of the labeled amount of Thyroxine Sodium | 100.25 %                                                        |

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

Analyzed by

Checked by

Approved by