

CERTIFICATE OF ANALYSIS

| | | | |
|----------------------|-------------------------------|--------------|------------|
| Product Name | LEVOTHYROXINE SODIUM Ph. Eur. | | |
| Reference | Ph. Eur. / In house | Mfg. Date | 01/09/2018 |
| Batch No. | 4001/3/010/18 | Expiry Date | 30/08/2021 |
| Date of Analysis | 08/09/2018 | Dispatch Qty | ----- |
| Name of the Customer | ----- | | |

| S. No. | Test | Specification | Result |
|--------|--|--|---|
| 1. | Description | Almost white or slightly brownish-yellow, fine slightly hygroscopic, crystalline powder. | Almost white fine slightly hygroscopic, powder. |
| 2. | Solubility | | |
| | a) In water | Very slightly soluble in water | Complies |
| | b) In ethanol | Slightly soluble in ethanol (96%) | Complies |
| | c) In alkali hydroxides | It dissolves in dilute solutions of alkali hydroxides | Complies |
| 3. | Identification by | | |
| | A) IR | The IR absorption spectrum of sample should conform to that of standard. | Complies |
| | B) Test for sodium | Dense precipitate should be produced. Sodium compounds impart an intense yellow color to a non-luminous flame. | Complies |
| 4. | Appearance of solution | Solution S not more intensely colored than reference solution BY ₃ | Complies |
| 5. | Specific optical rotation(°) (on anhydrous basis) @ 25°C | Between +16 to +20 | +17.87 |
| 6. | Water content (%w/w) | Between 6.0 to 12.0 | 8.50 |
| 7. | Related Substances By HPLC (% w/w) | | |
| | Impurity-A | Not more than 1.0 | BRL |
| | Impurity-F | Not more than 0.5 | BRL |
| | Impurity-G | Not more than 0.3 | BRL |
| | Unspecified impurity | Not more than 0.2 | BRL |
| | Total Impurities | Not more than 2.0 | BRL |
| 8. | Assay By HPLC (%w/w) (On anhydrous basis) | Not less than 97.0 and Not more than 102.0 | 100.7 |
| 9. | Residual solvents(By HPLC in ppm) Test I | | |

| | Prepared By | Checked By | Approved By |
|---------------------|-------------------------------|-------------------------------------|--------------------------------------|
| Name | L .Dileep Kumar. | A. Sri Yashwanth. | K. Karuna Kumar |
| Designation & Dept. | Trainee | Executive-QAD | Asst. Manager - QAD |
| Sign & Date | <i>L. Dileep</i> 23/03/19. | <i>A. Sri Yashwanth</i> 23/03/19 | <i>K. Karuna Kumar</i> 23/03/2019 |

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| S. No. | Test | Specification | Result |
|--------|---|--------------------|--------------|
| | Acetic acid | Not more than 5000 | Not detected |
| 10. | Residual Solvents (By Headspace GC in ppm) Test II | | |
| | a) Methanol | Not more than 3000 | BDL |
| | b) Acetone | Not more than 5000 | BDL |
| | c) Isopropyl Alcohol | Not more than 5000 | BDL |
| | d) Acetonitrile | Not more than 410 | Not detected |
| | e) Methyl isobutyl ketone | Not more than 4500 | BDL |
| | f) Toluene | Not more than 890 | Not detected |
| 11. | g) Anisole | Not more than 5000 | Not detected |
| | Residual Solvents (By Headspace GC in ppm) Test III | | |
| | Triethyl amine | Not more than 320 | Not detected |
| 12. | Particle size (Dry method)* | | |
| | D _(0.9) | For information | 5.096 µm |

*As per Customer Requirement.

Packaging and Storage Conditions: Finished product shall be packed in transparent LDPE bag with nitrogen purging, and tied with nylon strip followed by black LDPE bag along with silica gel desiccant and tied with nylon strip followed by triple laminated bag along with O-buster and hot seal and followed by HDPE container with clamp.

Store in an airtight container, protected from light, at a temperature of 2° to 8°C.

Chemical name of the impurities:

Impurity-A: (2S)-2-Amino-3-[4-(4-hydroxy-3-iodophenoxy)-3, 5-diiodophenyl] propanoic acid. (Liothyronine)

Impurity-F: (2S)-2-Amino-3-[4-[4-[4-hydroxy-3, 5-diiodophenoxy)-3, 5-diiodophenoxy]-3, 5-diiodophenyl] propanoic acid.

Impurity-G: Unknown structure.

Remarks: The Material Complies as per the above Specification.

| | | | |
|---------------------|------------------------|-------------------------------|-------------------------------|
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| Name | L. Dileep Kumar. | A. Sri Yashwanth. | K. Karuna Kumar |
| Designation & Dept. | Trainee | Executive-QAD | Asst. Manager - QAD |
| Sign & Date | L. Dileep 23/03/19. | A. Sri Yashwanth 23/03/19. | K. Karuna Kumar 23/03/2019 |