



ANG LIFESCIENCES INDIA LTD.
 Village- Kishanpura, Nalagarh Road, Tehsil: Baddi District: Solan, H.P.-174101
Certificate of Analysis

Product Name: Thiopton-1g (Thiopentone Injection IP 1000 mg)

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| Batch No. | : AA174003 | A. R. No. | : FP/24/0275 |
| Mfg. Date | : 04/2024 | Analysis date | : 16/04/2024 |
| Exp. Date | : 09/2026 | Released Date | : 30/04/2024 |
| Sampled Qty. | : 41 vials | Sampled By | : IPQA |
| Batch Size | : 9578 vials | | |

| S.No. | Test | Specifications | Observations |
|-------|--|---|---|
| 1 | Description | A Yellowish white powder Hygroscopic, filled in 20 ml clear type-III, glass vials, plugged with Grey/bromo butyl rubber plugs & sealed with pink-c colored F/O aluminium seals. | A Yellowish white powder, Hygroscopic, filled in 20 ml clear type-III, glass vials, plugged with grey butyl rubber plugs & sealed with pink-c coloured F/O aluminium seals. |
| 2 | Identification B. Identification of Barbiturates | Complies with the test for Identification of Barbiturates. | Complies |
| | C. Melting test | The Crystals melt at about 160°. | Complies |
| | D. Colour Test | A reddish violet colour is produced. | Complies |
| | E. Sodium Test | A dense, white precipitate is formed | Complies |
| 3 | Average Fill weight | 1037.79 mg ± 5 % | 1036.42 mg |
| 4 | Uniformity of weight | ± 10 % of average fill weight. | +1.16% -1.66% |
| 5 | Appearance of solution | A 10%w/v solution is clear and not more intensely coloured than reference solution GYS3 | Complies |
| 6 | Loss on drying | Not more than 2.5 % | 1.16% |
| 7 | Particulate Matter A. Visible | Constituted solution is essentially free from particle of foreign matter that can be observed on visual inspection. | Free from particulate matter |
| | B. Sub Visible | Particle Size ≥ 10µm/container- NMT 6000 Particle Size ≥ 25µm/container- NMT 600 | Complies Complies |
| 8 | Constituted Solution A. Completeness of solution | The solid should dissolve completely, leaving no visible residue as undissolved matter. | Complies |
| | B. Clarity of solution | The constituted solution should not be significantly less clear than an equal volume of the diluents contained in a similar vessel and examined similarly | Complies |
| 9 | Bacterial Endotoxins | NMT 1.0 EU/mg | Less than 1.0 EU/mg |
| 10 | Sterility | Should be sterile | Complies |
| 11 | Related substance Impurity A | Not more than 0.1% | Not Detected |
| | Impurity B | Not more than 1.0% | Not Detected |
| | Impurity C | Not more than 3.0% | Not Detected |
| | Impurity D | Not more than 0.3% | Not Detected |
| | Any Individual Impurity | Not more than 0.1% | Not Detected |
| | Total Impurity | Not more than 5.0% | Not Detected |
| 12 | Assay Each vial contains: Thiopentone Sodium IP 1000 mg Contains Sodium Carbonate as buffer | Between 770.0mg to 920.0mg (For Thiopentone: 77.0% to 92.0%) (For sodium: 9.4% to 11.8%) | 888.64 mg (88.86%) (10.24%) |

Conclusion: - The above Batch Complies/Does not comply as per IP & IH Specifications.

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| Analyzed By: Date: <u>30/04/2024</u> | Checked By: Date: <u>30/04/2024</u> | Approved By: Date: <u>for 30/04/2024</u> |
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