

| Title        |                                                                                                    | Certificate of Analysis Finished Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                               |
|--------------|----------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| Product Name | THIOPTON Injection                                                                                 | A.R. No.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | ARN/FP/26/031                                                                 |
| Generic Name | Thiopentone Injection IP 500mg                                                                     | Sampled qty.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 45 Vials                                                                      |
| Batch No.    | ARN2644A                                                                                           | Sampled by                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Rakesh                                                                        |
| Batch Size   | 5000Vials                                                                                          | Sampled on                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 06/07/2026                                                                    |
| Mfg. Date    | 07/2026                                                                                            | Date of Testing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 07/07/2026                                                                    |
| Exp. Date    | 06/2028                                                                                            | Date of Release                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 24/07/2026                                                                    |
| S. No.       | Tests                                                                                              | Specifications                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Observations                                                                  |
| 1.           | Description                                                                                        | A yellowish white dry powder filled in clear glass vial.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | A yellowish white dry powder filled in clear glass vial.                      |
| 2.           | Identification<br><br>(By IR)<br><br>(By Chemically)<br><br>(By Chemically)<br><br>(By Chemically) | <p><b>Test A may be omitted if tests B, C, D and E carried out Tests B and D may be omitted if tests A, C and E are carried out.</b></p> <p><b>A.</b> Compare the spectrum with that obtained with thiopentone IPRS or with the reference spectrum of thiopentone.</p> <p><b>B.</b> Complies with the test for identification of barbiturates, but using the following solutions.</p> <p>Test solution. 0.1%w/v solution of the substance under examination in water.</p> <p>Reference solution. Dissolve 85mg of thiopentone IPRS in 10ml of 2 M sodium hydroxide and dilute to 100ml with water.</p> <p><b>C.</b> The crystals melt at about 160°.</p> <p><b>D.</b> Dissolve 1mg of the crystals obtained in test A in 1ml of 0.1 M sodium hydroxide. Add about 1mg of sodium nitroprusside and, after 15 minutes, 1ml of dilute hydrochloric acid; a reddish violet colour is produced.</p> <p><b>E.</b> It gives the reactions of sodium salts.</p> | <p>Complies</p> <p>omitted</p> <p>Complies</p> <p>omitted</p> <p>Complies</p> |
| 3.           | Uniformity of Weight                                                                               | Average weight $\pm 10\%$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | -1.70% & +2.45%                                                               |
| 4.           | Average weight                                                                                     | Informative.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 530.4 mg                                                                      |
| 5.           | Loss on dry                                                                                        | NMT 2.5%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 1.83%                                                                         |

Analysis by 24/07/26  
NAME: NIKHIL SHARMA

Checked by 24/07/26  
NAME: SURJEET KAUR

Approved by 24/07/26  
NAME: MRS. SWATI DHAWAN

**Title**
**:**
**Certificate of Analysis Finished Product**

|                     |                                |                        |               |
|---------------------|--------------------------------|------------------------|---------------|
| <b>Product Name</b> | <b>THIOPTON Injection</b>      | <b>A.R. No.</b>        | ARN/FP/26/031 |
| <b>Generic Name</b> | Thiopentone Injection IP 500mg | <b>Sampled qty.</b>    | 45 Vials      |
| <b>Batch No.</b>    | ARN2644A                       | <b>Sampled by</b>      | Rakesh        |
| <b>Batch Size</b>   | 5000Vials                      | <b>Sampled on</b>      | 06/07/2026    |
| <b>Mfg. Date</b>    | 07/2026                        | <b>Date of Testing</b> | 07/07/2026    |
| <b>Exp. Date</b>    | 06/2028                        | <b>Date of Release</b> | 24/07/2026    |

|                                 |                                                                                                                                                                        |                                                                                                                                                                                                                  |                                            |
|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| 6.                              | Appearance of Solution                                                                                                                                                 | A 10.0 per cent w/v solution in carbondioxide-free water (solution A) is clear and not more intensely coloured than reference solution GYS3.                                                                     | Complies                                   |
| 7.                              | Related Substance (By HPLC)                                                                                                                                            |                                                                                                                                                                                                                  |                                            |
| A                               | Thiopentone Impurity A                                                                                                                                                 | NMT 0.1%                                                                                                                                                                                                         | 0.011%                                     |
| B                               | Thiopentone Impurity B                                                                                                                                                 | NMT 1.0%                                                                                                                                                                                                         | Not Detected                               |
| C                               | Thiopentone Impurity C                                                                                                                                                 | NMT 3.0%                                                                                                                                                                                                         | 0.017%                                     |
| D                               | Thiopentone Impurity D                                                                                                                                                 | NMT 0.3%                                                                                                                                                                                                         | 0.081%                                     |
| E                               | Any other secondary peak                                                                                                                                               | NMT 0.1%                                                                                                                                                                                                         | 0.042%                                     |
| F                               | Sum of any secondary peaks                                                                                                                                             | NMT 5.0%                                                                                                                                                                                                         | 0.151%                                     |
| 8.                              | Particulate Matter<br>(A.) Light Obscuration particle count test<br>(1.) Particles $\geq 10\mu\text{m}$<br>(2.) Particles $\geq 25\mu\text{m}$<br>(B.) Visual Particle | NMT 6000/Vials<br>NMT 600/Vials<br>The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye. | 2,195/Vials<br>2/Vials<br>Complies         |
| 9.                              | Sterility                                                                                                                                                              | No microbial growth should be observed.                                                                                                                                                                          | Complies                                   |
| 10.                             | Bacterial Endotoxins                                                                                                                                                   | NMT 1.0 EU/mg of Thiopentone Sodium.                                                                                                                                                                             | Less than 1.0 EU/mg of Thiopentone Sodium. |
| 11.                             | Assay: (By HPLC)<br>Each glass vial Contains:                                                                                                                          |                                                                                                                                                                                                                  |                                            |
| Ingredients                     |                                                                                                                                                                        | Found                                                                                                                                                                                                            | Limits % of labelled amount                |
| For Thiopentone                 |                                                                                                                                                                        | 89.52%                                                                                                                                                                                                           | NLT 77.0% NMT 92.0%                        |
| For Sodium                      |                                                                                                                                                                        | 10.80%                                                                                                                                                                                                           | NLT 9.4% NMT 11.8%                         |
| Total Thiopentone Sodium        | Labelled claim                                                                                                                                                         | Found                                                                                                                                                                                                            | %of labelled amount                        |
| Thiopentone Sodium (sterile) IP | 500mg                                                                                                                                                                  | 501.5829mg                                                                                                                                                                                                       | 100.32%                                    |

**Remarks:** In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/BP/USP/WHO.

Analysis by

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