

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

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

|                     |                              |                        |               |
|---------------------|------------------------------|------------------------|---------------|
| <b>Product Name</b> | <b>THIOPTON Injection</b>    | <b>A.R. No.</b>        | ARN/FP/26/053 |
| <b>Generic Name</b> | Thiopentone Injection IP 1gm | <b>Sampled qty.</b>    | 45 Vials      |
| <b>Batch No.</b>    | ARN2677A                     | <b>Sampled by</b>      | Rakesh        |
| <b>Batch Size</b>   | 7300 Vials                   | <b>Sampled on</b>      | 21/08/2026    |
| <b>Mfg. Date</b>    | 08/2026                      | <b>Date of Testing</b> | 22/08/2026    |
| <b>Exp. Date</b>    | 07/2028                      | <b>Date of Release</b> | 05/09/2026    |

| 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>(By Chemically)<br><br>(By Chemically) | <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><br><b>A.</b> Compare the spectrum with that obtained with thiopentone IPRS or with the reference spectrum of thiopentone.<br><b>B.</b> Complies with the test for identification of barbiturates, but using the following solutions.<br>Test solution. 0.1%w/v solution of the substance under examination in water.<br>Reference solution. Dissolve 85mg of thiopentone IPRS in 10ml of 2 M sodium hydroxide and dilute to 100ml with water.<br><b>C.</b> The crystals melt at about 160°.<br><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.<br><b>E.</b> It gives the reactions of sodium salts. | Complies<br><br>Omitted<br><br>Complies<br>Omitted<br><br>Complies |
| 3.     | Uniformity of Weight                                                                                                  | Average weight $\pm 10\%$                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | -3.74% & +2.56%                                                    |
| 4.     | Average weight                                                                                                        | Informative.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 1045.7 mg                                                          |
| 5.     | Loss on dry                                                                                                           | NMT 2.5%                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 1.83%                                                              |

Analysis by

NAME: MOHD. ZAID

Checked by

NAME: SURJEET KAUR

Approved by

NAME: MRS. SWATI DHAWAN

**Title**

:

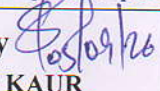
**Certificate of Analysis Finished Product**

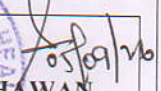
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|                                 |                                                                                                                                                                        |                                                                                                                                              |                                             |
|---------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| 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%                                                                                                                                     | Not Detected                                |
| B                               | Thiopentone Impurity B                                                                                                                                                 | NMT 1.0%                                                                                                                                     | Not Detected                                |
| C                               | Thiopentone Impurity C                                                                                                                                                 | NMT 3.0%                                                                                                                                     | Not Detected                                |
| D                               | Thiopentone Impurity D                                                                                                                                                 | NMT 0.3%                                                                                                                                     | 0.115%                                      |
| E                               | Any other secondary peak                                                                                                                                               | NMT 0.1%                                                                                                                                     | 0.082%                                      |
| F                               | Sum of any secondary peaks                                                                                                                                             | NMT 5.0%                                                                                                                                     | 0.320%                                      |
| 8.                              | Particulate Matter<br>(A.) Visible particulate matter<br>(B.) Sub-Visible particle count<br>(1.) Particles $\geq 10\mu\text{m}$<br>(2.) Particles $\geq 25\mu\text{m}$ | Should Free from any type of visual particles<br><br>NMT 6000/vial<br>NMT 600/vial                                                           | Complies<br><br>2,727/vial<br>3/vial        |
| 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                 |                                                                                                                                                                        | 87.92%                                                                                                                                       | NLT 77.0% NMT 92.0%                         |
| For Sodium                      |                                                                                                                                                                        | 11.08%                                                                                                                                       | NLT 9.4% NMT 11.8%                          |
| Total Thiopentone Sodium        | Labelled claim                                                                                                                                                         | Found                                                                                                                                        | %of labelled amount                         |
| Thiopentone Sodium (sterile) IP | 1000mg                                                                                                                                                                 | 989.9273 mg                                                                                                                                  | 98.99%                                      |
|                                 |                                                                                                                                                                        |                                                                                                                                              | Limits % of labelled amount                 |
|                                 |                                                                                                                                                                        |                                                                                                                                              | 90.0% to 110.0%                             |

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/HHS.

Analysis by   
NAME: MOHD. ZAÏD

Checked by   
NAME: SURJEET KAUR

Approved by   
NAME: MRS. SWATI DHAWAN