



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Title

Certificate of Analysis Finished Product

Product Name	Thioputon Injection	A.R. No.	ARN/FP/25/029
Generic Name	Thiopentone Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARN2533A	Sampled by	Anuj Verma
Batch Size	25,000 Vials	Sampled on	30/09/2025
Mfg. Date	09/2025	Date of Testing	01/10/2025
Exp. Date	08/2027	Date of Release	17/10/2025

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 (By IR) (By Chemically) (By Chemically) (By Chemically)	<p>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.</p> <p>A. Compare the spectrum with that obtained with thiopentone IPRS or with the reference spectrum of thiopentone.</p> <p>B. Complies with the test for identification of barbiturates, but using the following solutions. Test solution. 0.1%w/v solution of the substance under examination in water. Reference solution. Dissolve 85mg of thiopentone IPRS in 10ml of 2 M sodium hydroxide and dilute to 100ml with water.</p> <p>C. The crystals melt at about 160°.</p> <p>D. 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>E. It gives the reactions of sodium salts.</p>	Complies ✓ Omitted 160.2° Omitted Complies
3.	Uniformity of Weight	Average weight ±10%	-2.21% & +2.51%
4.	Average weight	Informative.	1057.9 mg
5.	Loss on dry	NMT 2.5%	0.91%

Analysis by *Nikhil Sharma*
NAME: NIKHIL SHARMA

Checked by *Sufiyan Ansari*
NAME: SUFIYAN ANSARI

Approved by *Swati Dhawan*
NAME: MRS. SWATI DHAWAN



Title

:

Certificate of Analysis Finished Product

Product Name	Thiopton Injection	A.R. No.	ARN/FP/25/029
Generic Name	Thiopentone Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARN2533A	Sampled by	Anuj Verma
Batch Size	25,000 Vials	Sampled on	30/09/2025
Mfg. Date	09/2025	Date of Testing	01/10/2025
Exp. Date	08/2027	Date of Release	17/10/2025

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	
	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%	Not detected	
E	Any other secondary peak	NMT 0.1%	Not detected	
F	Sum of any secondary peaks	NMT 5.0%	Not detected	
8.	Particulate Matter (A.) Visible particulate matter (B.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	Should Free from any type of visual particles NMT 6000/vial NMT 600/vial	Complies 1244/vial 8/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) Each glass vial Contains:			
Ingredients		Found	Limits % of labelled amount	
For Thiopentone		90.58%	NLT 77.0% NMT 92.0%	
For Sodium		10.46%	NLT 9.4% NMT 11.8%	
Total Thiopentone Sodium	Labelled claim	Found	%of labelled amount	Limits % of labelled amount
Thiopentone Sodium (sterile) IP	1000mg	1010.42 mg	101.04%	-

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/IHS.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: MRS. SWATI DHAWAN
------------------------------------	------------------------------------	--