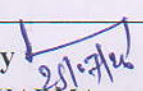
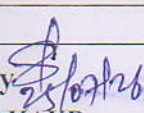
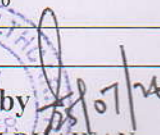


**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

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

Title		Certificate of Analysis Finished Product	
Product Name	THIOPTON Injection	A.R. No.	ARN/FP/26/033
Generic Name	Thiopentone Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	ARN2645A	Sampled by	Rakesh
Batch Size	5000Vials	Sampled on	07/07/2026
Mfg. Date	07/2026	Date of Testing	08/07/2026
Exp. Date	06/2028	Date of Release	25/07/2026
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 (By IR) (By Chemically) (By Chemically) (By Chemically)	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. A. Compare the spectrum with that obtained with thiopentone IPRS or with the reference spectrum of thiopentone. 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. C. The crystals melt at about 160°. 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. E. It gives the reactions of sodium salts.	Complies omitted Complies omitted Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-9.08% & +2.53%
4.	Average weight	Informative.	529.9 mg
5.	Loss on dry	NMT 2.5%	1.84%

Analysis by 
NAME: NIKHIL SHARMAChecked by 
NAME: SURJEET KAURApproved by 
NAME: MRS. SWATI DHAWAN

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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%	0.026%
D	Thiopentone Impurity D	NMT 0.3%	0.087%
E	Any other secondary peak	NMT 0.1%	0.045%
F	Sum of any secondary peaks	NMT 5.0%	0.157%
8.	Particulate Matter (A.) Light Obscuration particle count test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Vials NMT 600/Vials The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	2,637/Vials 9/Vials 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) Each glass vial Contains:		
Ingredients		Found	Limits % of labelled amount
For Thiopentone		89.02%	NLT 77.0% NMT 92.0%
For Sodium		10.78%	NLT 9.4% NMT 11.8%
Total Thiopentone Sodium	Labelled claim	Found	%of labelled amount
Thiopentone Sodium (sterile) IP	500mg	499.0356 mg	99.81%

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/HIS.

Analysis by NAME: NIKHIL SHARMA	Checked by NAME: SURJEET KAUR	Approved by NAME: MRS. SWATI DHAWAN
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