



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/25/106
Generic Name	Thiopentone Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARN25117A	Sampled by	Anuj Verma
Batch Size	35,000 Vials	Sampled on	17/03/2026
Mfg. Date	03/2026	Date of Testing	18/03/2026
Exp. Date	02/2028	Date of Release	02/04/2026

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) (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>	<p>Complies</p> <p>Omitted</p> <p>Complies</p> <p>Omitted</p> <p>Complies</p>
3.	Uniformity of Weight	Average weight $\pm 10\%$	-1.47% & +2.17%
4.	Average weight	Informative.	1041.4 mg
5.	Loss on dry	NMT 2.5%	91%

Analysis by 02/04/2026 NAME: NIKHIL SHARMA	Checked by 02/04/26 NAME: RAMANJEET SINGH	Name : Mrs. Swati Dhanwan Designation : QC HOD Qualification : M.Sc. Clinical Microbiology Registered Pharmacist Approved by 02/04/26 NAME: MRS. SWATI DHAWAN
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6.	Appearance of Solution	A 10.0 per cent w/v solution in carbon dioxide-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%	0.269%
E	Any other secondary peak	NMT 0.1%	0.088%
F	Sum of any secondary peaks	NMT 5.0%	0.300%
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 412/vial 4/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		86.32%	NLT 77.0% NMT 92.0%
For Sodium		11.09%	NLT 9.4% NMT 11.8%
Total Thiopentone Sodium	Labelled claim	Found	%of labelled amount
Thiopentone Sodium (sterile) IP	1000mg	974.0743 mg	97.41%
			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/HS.

Analysis by 02/04/26
NAME: NIKHIL SHARMA

Checked by 02/04/26
NAME: RAMANJEET SINGH

Name: Mrs. Swati Dhawan
Qualification: M.Sc. Clinical Microbiology
Registered
Approved by 02/04/26
NAME: MRS. SWATI DHAWAN