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/26/034
Generic Name	Thiopentone Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	ARN2642A	**Sampled by**	Aakash
Batch Size	10,000 Vials	**Sampled on**	08/07/2026
Mfg. Date	07/2026	**Date of Testing**	09/07/2026
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	**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.**	
	(By IR)	**A.** Compare the spectrum with that obtained with thiopentone IPRS or with the reference spectrum of thiopentone.	Complies
	(By Chemically)	**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.	Omitted
	(By Chemically)	**C.** The crystals melt at about 160°.	Complies
	(By Chemically)	**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.	Omitted
	(By Chemically)	**E.** It gives the reactions of sodium salts.	Complies
3.	Uniformity of Weight	Average weight ±10%	-1.11% & +1.61%
4.	Average weight	Informative.	1044.7 mg
5.	Loss on dry	NMT 2.5%	1.75%

Analysis by	Checked by	Approved by
25/07/26	25/07/26	25/07/26
NAME: NIKHIL SHARMA	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN

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Care & Cure with Research

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6.	Appearance of Solution	A 10.0 per cent w/v solutuion in carbondioxide-free water (solution A) is clear and not more intensly coloured than reference solution GYS3.	Complies
7.	Related Substance (By HPLC)		
A	Thiopentone Impurity A	NMT 0.1%	0.012%
B	Thiopentone Impurity B	NMT 1.0%	Not Detected
C	Thiopentone Impurity C	NMT 3.0%	0.021%
D	Thiopentone Impurity D	NMT 0.3%	0.085%
E	Any other secondary peak	NMT 0.1%	0.041%
F	Sum of any secondary peaks	NMT 5.0%	0.159%
8.	Particulate Matter		
	(A.)Visible particulate matter	Should Free from any type of visual particles	Complies
	(B.) Sub-Visible particle count		
	(1.) Particles ≥10µm	NMT 6000/vial	2,005/vial
	(2.) Particles ≥25µm	NMT 600/vial	11/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			88.44%	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	Limits % of labelled amount
Thiopentone Sodium (sterile) IP	1000mg	992.2194 mg	99.22%	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	Checked by	Approved by
NAME: NIKHIL SHARMA	NAME: SURJEET KAUR	NAME: MRS. SWATI DHAWAN