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**-500mg Injection	**A.R. No.**	ARN/FP/25/060
Generic Name	Thiopentone Injection IP 500mg	**Sampled qty.**	45 Vials
Batch No.	ARN2563A	**Sampled by**	Anuj Verma
Batch Size	10,000Vials	**Sampled on**	29/11/2025
Mfg. Date	11/2025	**Date of Testing**	01/12/2025
Exp. Date	10/2027	**Date of Release**	20/12/2025

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	**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.	Complies
	(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.	Complies
	(By Chemically)	**E.** It gives the reactions of sodium salts.	Complies
3.	Uniformity of Weight	Average weight ±10%	-1.10% & +0.90%
4.	Average weight	Informative.	524.3 mg
5.	Loss on dry	NMT 2.5%	1.77%

Analysis by	Checked by	Approved by
NAME: NIKHIL SHARMA 20/12/2025	NAME: SUFIYAN ANSARI 20/12/25	NAME: MRS. SWATI DHAWAN

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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%	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.) Light Obscuration particle count test (1.) Particles ≥10µm (2.) Particles ≥25µm	NMT 6000/Vials NMT 600/Vials	577/Vials 1/Vials
	(B.)Visual Particle	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	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		90.10%	NLT 77.0% NMT 92.0%
For Sodium		10.43%	NLT 9.4% NMT 11.8%
Total Thiopentone Sodium	Labelled claim	Found	%of labelled amount / Limits % of labelled amount
Thiopentone Sodium (sterile) IP	500mg	502.63 mg	100.53% / -

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	Checked by	Approved by
NAME: NIKHIL SHARMA 20/12/2025	NAME: SUFIYAN ANSARI 20/12/25	NAME: MRS. SWATI DHAWAN

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