



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

Certificate of Analysis Finished Product

Title		:	Ceramics	
Product Name	THIOPTON Injection		A.R. No.	ARN/FP/26/035
Generic Name	Thiopentone Injection IP 1gm		Sampled qty.	45 Vials
Batch No.	ARN2643A		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
			Observations	

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 $\pm 10\%$	-2.33% & +3.05%
4.	Average weight	Informative.	1037.1 mg
5.	Loss on dry	NMT 2.5%	1.77%

Analysis by
NAME: NIKHIL SHARMA

Checked by
NAME: SURJEET KAUR

Approved by
NAME: MRS. SWATI DHAWAN

Title

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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%	0.012%
B	Thiopentone Impurity B	NMT 1.0%	Not Detected
C	Thiopentone Impurity C	NMT 3.0%	0.025%
D	Thiopentone Impurity D	NMT 0.3%	0.089%
E	Any other secondary peak	NMT 0.1%	0.045%
F	Sum of any secondary peaks	NMT 5.0%	0.171%
8.	Particulate Matter		
	(A.) Visible particulate matter	Should Free from any type of visual particles	Complies
	(B.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	1,984/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/vial	13/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		87.69%		NLT 77.0% NMT 92.0%
For Sodium		10.82%		NLT 9.4% NMT 11.8%
Total Thiopentone Sodium	Labelled claim	Found	%of labelled amount	Limits % of labelled amount
Thiopentone Sodium (sterile) IP	1000mg	985.0747 mg	98.51%	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 NAME: NIKHIL SHARMA	Checked by NAME: SURJEET KAUR	Approved by NAME: MRS. SWATI DHAWAN
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