

Title

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Certificate of Analysis Finished Product

Product Name	THIOPTON Injection	A.R. No.	ARN/FP/26/052
Generic Name	Thiopentone Injection IP 1gm	Sampled qty.	45 Vials
Batch No.	ARN2676A	Sampled by	Rakesh
Batch Size	10,000 Vials	Sampled on	21/08/2026
Mfg. Date	08/2026	Date of Testing	22/08/2026
Exp. Date	07/2028	Date of Release	05/09/2026

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. 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 $\pm 10\%$	-1.25% & +1.25%
4.	Average weight	Informative.	1045.0 mg
5.	Loss on dry	NMT 2.5%	1.69%

Analysis by *[Signature]*
NAME: MOHD. ZAID

Checked by *[Signature]*
NAME: SURJEET KAUR

Approved by *[Signature]*
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%	0.121%
E	Any other secondary peak	NMT 0.1%	0.083%
F	Sum of any secondary peaks	NMT 5.0%	0.326%
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 2,829/vial 9/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		85.98%	NLT 77.0% NMT 92.0%
For Sodium		11.22%	NLT 9.4% NMT 11.8%
Total Thiopentone Sodium	Labelled claim	Found	% of labelled amount
Thiopentone Sodium (sterile) IP	1000mg	972.0203 mg	97.20%
			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/IHS.

Analysis by NAME: MOHD. ZAID	Checked by NAME: SURJEET KAUR	Approved by NAME: MRS. SWATI DHAWAN
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