

Title

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Certificate of Analysis Finished Product

Product Name	Thioputon Injection	A.R. No.	NB/FP/25/150
Generic Name	Thiopentone Injection IP 1g	Sampled qty.	45 Vials
Batch No.	N25137A	Sampled by	Anuj Verma
Batch Size	25,040 Vials	Sampled on	21/07/2025
Mfg. Date	06/2025	Date of Testing	21/07/2025
Exp. Date	05/2027	Date of Release	05/08/2025

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 (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>160.1° Omitted</p> <p>Complies</p>
3.	Uniformity of Weight	Average weight $\pm 10\%$	-5.19% & +2.49%
4.	Average weight	Informative.	1059.0 mg
5.	Loss on dry	NMT 2.5%	1.14%

Analysis by

NAME: NIKHIL SHARMA

Checked by

NAME: SUFIYAN ANSARI

NAME: SWATI BHAWAN



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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 intently 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.) 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 2231/vial 5/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	88.97%	NLT 77.0% NMT 92.0%
For Sodium	10.63%	NLT 9.4% NMT 11.8%
Total Thiopentone Sodium	Labelled claim	Found %of labelled amount
Thiopentone Sodium (sterile) IP	1000mg	996.0mg 99.60%

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/AHS.

Analysis by <i>Nikhil Sharma</i> NAME: NIKHIL SHARMA	Checked by <i>Sufiyan Ansari</i> NAME: SUFIYAN ANSARI	Approved by <i>Swati Dhawan</i> NAME: SWATI DHAWAN
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