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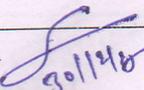
Surajpur, Paonta sahib Dist. Sirmour (H.P)

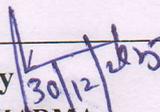
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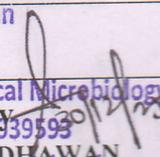
Certificate of Analysis Finished Product

Product Name	THIOPTON Injection	A.R. No.	NB/FP/25/278
Generic Name	Thiopentone Injection IP 1000mg	Sampled qty.	45 Vials
Batch No.	N25317A	Sampled by	Dhananjay
Batch Size	10,500 Vials	Sampled on	14/12/2025
Mfg. Date	12/2025	Date of Testing	14/12/2025
Exp. Date	11/2027	Date of Release	30/12/2025

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 (By IR) (By Chemically) (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 160.2° Omitted Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-1.75% & +0.90%
4.	Average weight	Informative $\pm 2\%$.	1049.4 mg
5.	Loss on dry	NMT 2.5%	1.35%

Analysis by 
NAME: SUFIYAN ANSARI

Checked by 
NAME: NIKHIL SHARMA

Name: Mrs. Swati Dhawan
Designation: QC HOD
Qualification: M.Sc. Clinical Microbiology
Registration No.: 530408939593
Approved by 
NAME: MRS. SWATI DHAWAN
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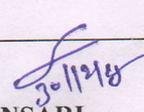
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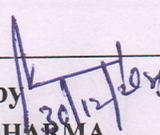
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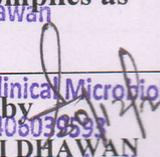
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6.	Appearance of Solution	A 10.0 per cent w/v solution in carbon dioxide-free water (solution A) is clear and not more intensely coloured than reference solution GYS3.	Complies	
7.	Related Substance (By HPLC)			
A	Thiopentone Impurity A	NMT 0.1%	Not 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%	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 $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Vials NMT 600/Vials The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	341/Vials 0/Vials	
9.	Sterility	No microbial growth should be observed.	Complies	
10.	Bacterial Endotoxins	NMT 1.0 EU/mg of Thiopentone.	Less than 1.0 EU/ mg of Thiopentone.	
11.	Assay: (By HPLC) Each glass vial contains:			
Ingredients		Found	Limits % of labeled amount	
For Thiopentone		85.97%	NLT 77.0% NMT 92.0%	
For Sodium		11.50%	NLT 9.4% NMT 11.8%	
Total Thiopentone Sodium	Labeled claim	Found	% of labeled amount	Limits % of labeled amount
Thiopentone Sodium (sterile) IP	1000mg	974.74 mg	97.47%	-

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/THS.

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