

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	THIOPTON Injection	A.R. No.	NB/FP/25/149
Generic Name	Thiopentone Injection IP 500mg	Sampled qty.	45 Vials
Batch No.	N25155A	Sampled by	Rakesh
Batch Size	5000 Vials	Sampled on	19/07/2025
Mfg. Date	07/2025	Date of Testing	19/07/2025
Exp. Date	06/2027	Date of Release	07/08/2025

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)	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 160.1° Omitted Complies
3.	Uniformity of Weight	Average weight $\pm 10\%$	-2.87% & +2.43%
4.	Average weight	Informative $\pm 2\%$.	512.1 mg
5.	Loss on dry	NMT 2.5%	1.38%

Analysis by

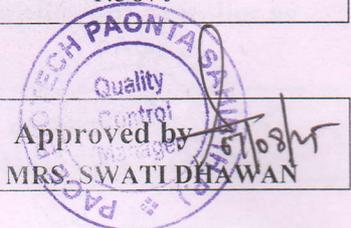
NAME: SUFIYAN ANSARI

Checked by

NAME: NIKHIL SHARMA

Approved by

NAME: MRS. SWATI DHAWAN



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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%	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	Should Free from any type of visual particles	Complies
	(b.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT 6000/vial	1721/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/vial	0/vial
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			
For Thiopentone		Found	Limits % of labeled amount
For Sodium		85.21%	NLT 77.0% NMT 92.0%
Total Thiopentone Sodium	Labeled claim	10.46%	NLT 9.4% NMT 11.8%
Thiopentone Sodium (sterile) IP	500mg	478.35mg	95.67%

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: SUFIYAN ANSARI	Checked by NAME: NIKHIL SHARMA	Approved by NAME: MRS. SWATI DHAWAN
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