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Pace Biotech

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

Title : Certificate of Analysis Finished Product

Product Name	**THIOPTON** Injection	**A.R. No.**	NB/FP/25/220
Generic Name	Thiopentone Injection IP 1gm	**Sampled qty.**	45 Vials
Batch No.	N25230D	**Sampled by**	Rakesh
Batch Size	6,250 Vials	**Sampled on**	30/09/2025
Mfg. Date	09/2025	**Date of Testing**	30/09/2025
Exp. Date	08/2027	**Date of Release**	17/10/2025

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	**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.**	
	(By IR)	**A.** Compare the spectrum with that obtained with thiopentone IPRS or with the reference spectrum of thiopentone.	Complies
	(By Chemically)	**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.	Omitted
	(By Chemically)	**C.** The crystals melt at about 160°.	160.2^0
	(By Chemically)	**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.	Omitted
	(By Chemically)	**E.** It gives the reactions of sodium salts.	Complies
3.	Uniformity of Weight	Average weight ±10%	-0.94% & +1.61%
4.	Average weight	Informative.	1044.3 mg
5.	Loss on dry	NMT 2.5%	1.13%

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

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6.	Appearance of Solution	A 10.0 per cent w/v solutuion in carbondioxide-free water (solution A) is clear and not more intensly 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 ≥10µm	NMT 6000/vial	1141/vial
	(2.) Particles ≥25µm	NMT 600/vial	3/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			86.60%	NLT 77.0% NMT 92.0%
For Sodium			10.46%	NLT 9.4% NMT 11.8%
Total Thiopentone Sodium	Labelled claim	Found	%of labelled amount	Limits % of labelled amount
Thiopentone Sodium (sterile) IP	1000mg	970.55mg	97.06%	-

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	Checked by	Approved by
17/10/25	17/10/2025	17/10/25
NAME: SUFIYAN ANSARI	NAME: NIKHIL SHARM A	NAME: MRS. SWATI DHAWAN