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	**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.	Omitted
		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.	
	(By Chemically)	**C.** The crystals melt at about 160°.	160.1^0
	(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%	-2.87% & +2.43%
4.	Average weight	Informative ±2%.	512.1 mg
5.	Loss on dry	NMT 2.5%	1.38%

Analysis by	Checked by	Approved by
07/08/25	07/08/2025	07/08/25
NAME: SUFIYAN ANSARI	NAME: NIKHIL SHARMA	NAME: MRS. SWATI DHAWAN

PAONTA SAHIB Quality Control

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

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 (b.) Sub-Visible particle count (1.) Particles ≥10µm (2.) Particles ≥25µm	Should Free from any type of visual particles NMT 6000/vial NMT 600/vial	Complies 1721/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			Found	Limits % of labeled amount
For Thiopentone			85.21%	NLT 77.0% NMT 92.0%
For Sodium			10.46%	NLT 9.4% NMT 11.8%
Total Thiopentone Sodium	Labeled claim	Found	%of labeled amount	Limits % of labeled amount
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	Checked by	Approved by
07/08/25	07/08/2025	
NAME: SUFIYAN ANSARI	NAME: NIKHIL SHARMA	NAME: MRS. SWATI DHAWAN

PACE BIOTECH PAONTA SAHIB Quality Control