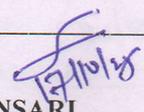


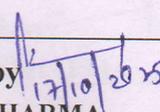
**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	THIOPTON Injection	<b>A.R. No.</b>	NB/FP/25/219
<b>Generic Name</b>	Thiopentone Injection IP 500mg	<b>Sampled qty.</b>	45 Vials
<b>Batch No.</b>	N25229B	<b>Sampled by</b>	Rakesh
<b>Batch Size</b>	4,300 Vials	<b>Sampled on</b>	30/09/2025
<b>Mfg. Date</b>	09/2025	<b>Date of Testing</b>	30/09/2025
<b>Exp. Date</b>	08/2027	<b>Date of Release</b>	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  (By IR)  (By Chemically)  (By Chemically) (By Chemically)  (By Chemically)	<p><b>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.</b></p> <p><b>A.</b> Compare the spectrum with that obtained with thiopentone IPRS or with the reference spectrum of thiopentone.</p> <p><b>B.</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><b>C.</b> The crystals melt at about 160°.</p> <p><b>D.</b> 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><b>E.</b> It gives the reactions of sodium salts.</p>	<p>Complies</p> <p>Omitted</p> <p>160.2° Omitted</p> <p>Complies</p>
3.	Uniformity of Weight	Average weight ±10%	-3.53% & +2.10%
4.	Average weight	Informative ±2%.	523.4 mg
5.	Loss on dry	NMT 2.5%	1.02%

Name : Mrs. Swati Dhawan  
 Designation : QC HOD  
 Qualification : M.Sc. Clinical Microbiology  
 Registration No. : 30040039593  
**Approved by**  
 NAME: MRS. SWATI DHAWAN

**Analysis by**   
 NAME: SUFIYAN ANSARI

**Checked by**   
 NAME: NIKHIL SHARMA

Title

:

**Certificate of Analysis Finished Product**

<b>Product Name</b>	THIOPTON Injection	<b>A.R. No.</b>	NB/FP/25/219
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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	1853/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT 600/vial	3/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		87.09%	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
Thiopentone Sodium (sterile) IP	500mg	487.75mg	97.55%

**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.**

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 5344033333

Punjab Technical University, Jalandhar

Analysis by

NAME: SUFIYAN ANSARI

Checked by

NAME: NIKHIL SHARMA

Approved by

NAME: MRS. SWATI DHAWAN