ANG LIFESCIENCES

ANG LIFESCIENCES INDIA LTD.

Village- Kishanpura, Nalagarh Road, Tehsil: Baddi District: Solan, H.P.-174101

Certificate of Analysis

Product Name: Thiopton (Thiopentone Injection IP 500mg)

Batch No.	:	AA164001		:	
Mfg. Date	:	04/2024	A. R. No.	:	FP/24/0385
Exp. Date	:	09/2026	Analysis date	:	30/04/2024
Sampled Qty.	:	41 vials	Released Date	:	14/05/2024
Batch Size	:	5200 vials	Sampled By	:	IPQA

S.No.	Test	Specifications	Observations
1	Description	A Yellowish white powder Hygroscopic, filled in 20 ml amber type-III, glass vials, plugged with Grey/bromo butyl rubber plugs & sealed with brown colored F/O aluminium seals.	A Yellowish white powder, Hygroscopic, filled in 20 ml clear type-III, glass vials, plugged with bromo butyl rubber plugs & sealed with brown coloured F/O aluminium seals.
2	Identification B. Identification of Barbiturates C. Melting test D. Colour Test E. Sodium Test	 Complies with the test for Identification of Barbiturates. The Crystals melt at about 160°. A reddish violet colour is produced. A dense, white precipitate is formed	 Complies Complies Complies Complies
3	Average Fill weight	518.62mg ± 5 %	517.11mg
4	Uniformity of weight	± 10 % of average fill weight.	+1.29% -0.99%
5	Appearance of solution	A 10%w/v solution is clear and not more intensely coloured than reference solution GYS3	Complies
6	Loss on drying	Not more than 2.5 %	1.35%
7	Particulate Matter A. Visible B. Sub Visible	 Constituted solution is essentially free from particle of foreign matter that can be observed on visual inspection. Particle Size ≥ 10µm/container- NMT 6000 Particle Size ≥ 25µm/container- NMT 600	 Free from particulate matter Complies Complies
8	Constituted Solution A. Completeness of solution B. Clarity of solution	 The solid should dissolve completely, leaving no visible residue as undissolved matter. The constituted solution should not be significantly less clear than an equal volume of the diluents contained in a similar vessel and examined similarly	 Complies Complies
9	Bacterial Endotoxins	NMT 1.0 EU/mg	Less than 1.0 EU/mg
10	Sterility	Should be sterile	Complies
11	Related substance Impurity A Impurity B Impurity C Impurity D Any Individual Impurity Total Impurity	 Not more than 0.1% Not more than 1.0% Not more than 3.0% Not more than 0.3% Not more than 0.1% Not more than 5.0%	 Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected
12	Assay Each vial contains: Thiopentone Sodium IP 500 mg Contains Sodium Carbonate as buffer	 Between 385.0mg to 460.0mg (For Thiopentone: 77.0% to 92.0%) (For sodium: 9.4% to 11.8%)	 444.49mg (88.90%) (10.20%)

Conclusion: - The above Batch Complies/~~Does not complies~~ as per IP & IH Specifications.

Analyzed By: **Date:** 14/05/2024	**Checked By:** **Date:** 14/05/2024	**Approved By:** **Date:** for 14/05/2024