



ANG LIFESCIENCES

ANG LIFESCIENCES INDIA LTD.

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

Certificate of Analysis

Product Name: Thiopton-1g (Thiopentone Injection IP 1000 mg)

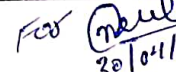
Batch No.	: AA174004	A. R. No.	: FP/24/0273
Mfg. Date	: 04/2024	Analysis date	: 16/04/2024
Exp. Date	: 09/2026	Released Date	: 30/04/2024
Sampled Qty.	: 41 vials	Sampled By	: IPQA
Batch Size	: 21444 vials		

S.No.	Test	Specifications	Observations
1	Description	A Yellowish white powder Hygroscopic, filled in 20 ml clear type-III, glass vials, plugged with Grey/bromo butyl rubber plugs & sealed with pink-c colored F/O aluminium seals.	A Yellowish white powder, Hygroscopic, filled in 20 ml clear type-III, glass vials, plugged with grey butyl rubber plugs & sealed with pink-c 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	1037.64 mg \pm 5 %	1036.80 mg
4	Uniformity of weight	\pm 10 % of average fill weight.	+1.12% -1.50%
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 %	1.10%
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 \geq 10 μ m/container- NMT 6000 Particle Size \geq 25 μ m/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 1000 mg Contains Sodium Carbonate as buffer	Between 770.0mg to 920.0mg (For Thiopentone: 77.0% to 92.0%) (For sodium: 9.4% to 11.8%)	888.80 mg (88.88%) (10.28%)

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

Analyzed By: 
Date: 30/04/2024

Checked By: 
Date: 30/04/2024

Approved By: 
Date: 30/04/2024