



Nixi Laboratories Pvt. Ltd.,
Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030,
Himachal Pradesh (INDIA).

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	Eptocan 250	AR. No.	NL/LA/FG/25/341
Generic Name	Phenytoin Sodium Injection USP		
Mother Batch No.	A25HE001	Reference	USP
Child Batch No.	A25HE001	Batch Size	10784 Ampoules
Mfg. Date	07/2025	Exp. Date	06/2027
Specification No. (STS No)	QC/LA/FG/STS/086	Standard Test Procedure No.	QC/LA/FG/STP/086
Sample Quantity	82 Ampoules	Sample Date	24/07/2025
Release Date	07/08/2025		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	A clear, colourless solution, free from foreign particles, filled in 5 ml Amber/clear colour glass ampoule.	A clear, colourless solution, free from foreign particles, filled in 5 ml Amber colour glass ampoule.
2.	Identification: (A) By Infrared Absorption Spectrophotometer (B) By HPLC	Compare the spectrum with that obtained with Phenytoin sodium WS or with the reference spectrum of Phenytoin sodium. (Residue obtained from the Sample meets the requirements.) The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Complies Complies
3.	Average Filled Volume	Not less than 5.0 ml	5.09 ml
4.	Extractable Volume	Not less than 5.0 ml	5.09 ml
5.	pH (At 25°C ±2°C)	10.0 to 12.3	11.05
6.	Particulate matter		
	Visible particles:	Should be free from visible particles	Complies
	For sub visible particles :		
	(i) Equal to or greater than 10µm	Not more than 6000 particles /container	9.0 particles/container
	(ii) Equal to or greater than 25µm	Not more than 600 particles /container	1.0 particles/container
7.	Sterility	Should comply the test of sterility	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Designation	Officer QC	Sr.Executive QC	Asst.Manager QC
Signature			
Date	07/08/25	07/08/25	07/08/25

Format No.: F/QC/013/03-04

Approved By
Name: Aditya Singh Page 1 of 2
Designation: Asst. Manager QC
Qualification: B.Sc
Enrollment No. II-009545
Avadh University Ayodhya



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8.	Bacterial Endotoxins	Not more than 0.3 USP Endotoxin Unit/mg of Phenytoin sodium.	Complies
9.	Alcohol And Propylene Glycol Content (a) Alcohol (b) Propylene glycol	9.0 %–11.0% 37.0 %–43.0%	10.25% 41.12%
10.	Assay: Each ml contains: Phenytoin Sodium IP 50 mg	47.50 mg to 52.50 mg (95.00% to 105.00%)	50.01 mg (100.02%)

RESULT: The above sample COMPLIES/DOES NOT COMPLY as per Specification No. QC/LA/FG/STS/086.

CONCLUSION: In the opinion of the under signed the sample referred above is of STANDARD QUALITY / IS NOT STANDARD QUALITY as defined in the Drugs & Cosmetics Act, 1940 and the rules made here under further.

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Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Designation	Officer QC	Sr.Executive QC	Asst.Manager QC
Signature			
Date	07/08/25	07/08/25	07/08/25

Format No.: F/QC/013/03-04

Approved By
Name: Aditya Singh
Designation: Asst. Manager
Qualification:
Enrollment No. 11-008045
Avadh University Ayodhya