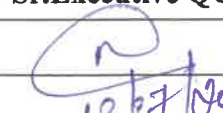
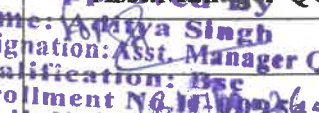


	Nixi Laboratories Pvt. Ltd., Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030, Himachal Pradesh (INDIA).		
	CERTIFICATE OF ANALYSIS FINISHED PRODUCTS		

Product Name	EPTOCAN 250	AR. No.	NL/LA/FG/26/336
Generic Name	Phenytoin Sodium Injection USP		
Mother Batch No.	A26HE001	Reference	USP
Child Batch No.	A26HE001B	Batch Size	20500 Ampoules
Mfg. Date	07/2026	Exp. Date	06/2028
Specification No. (STS No)	QC/LA/FG/STS/086-02	Standard Test Procedure No.	QC/LA/FG/STP/086
Sample Quantity	92 Ampoules	Sample Date	03/07/2026
Release Date	18/07/2026		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	A clear, colourless solution, free from foreign particles, filled in 2 ml Amber/clear colour glass ampoule.	A clear, colourless solution, free from foreign particles, filled in 2 ml Amber colour glass ampoule.
2.	Identification: (A) By Infrared Absorption Spectrophotometer	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.)	Complies
	(B) By HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.	Complies
3.	Average Filled Volume	Not less than 5.0 ml	5.10 ml
4.	Extractable Volume	Not less than 5.0 ml	5.10 ml
5.	pH (At 25°C ±2°C)	10.0 to 12.3	11.47
6.	Particulate matter		
	Visible particles:	Should be free from visible particles	Complies
	For sub visible particles : (i) Equal to or greater than 10µm (ii) Equal to or greater than 25µm	Not more than 6000 particles /container Not more than 600 particles /container	189.0 particles/container 19.0 particles/container
7.	Sterility	Should comply the test of sterility	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Ganesh Jaiswal	Meenakshi Panday	Aditya Singh
Designation	Sr.Executive QC	Sr.Executive QC	Asst. Manager QC
Signature			
Date	18/07/26	18/07/26	18/07/26

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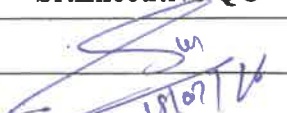
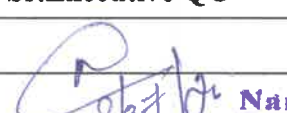
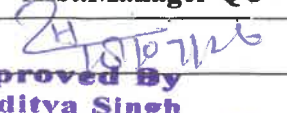
CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	EPTOCAN 250	AR. No.	NL/LA/FG/26/336
Generic Name	Phenytoin Sodium Injection USP		
Mother Batch No.	A26HE001	Reference	USP
Child Batch No.	A26HE001B	Batch Size	20500 Ampoules
Mfg. Date	07/2026	Exp. Date	06/2028
Specification No. (STS No)	QC/LA/FG/STS/086-02	Standard Test Procedure No.	QC/LA/FG/STP/086
Sample Quantity	92 Ampoules	Sample Date	03/07/2026
Release Date	18/07/2026		

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%	9.2443% 38.3608%
10.	Assay: Each ml contains: Phenytoin Sodium IP 50 mg	47.50 mg to 52.50 mg (95.00% to 105.00%)	52.42 mg (104.84%)
11.	Diethylene glycol and Ethylene glycol (By GC)	Not more than 0.1%	Not Detected

RESULT: The above sample **COMPLIES/DOES NOT COMPLY** as per Specification No.
QC/LA/FG/STS/086-02.

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.

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Ganesh Jaiswal	Meenakshi Panday	Aditya Singh
Designation	Sr.Executive QC	Sr.Executive QC	Asst.Manager QC
Signature			
Date	18/07/26	18/07/26	18/07/26

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

Approved By
Name: Aditya Singh
Designation: Asst. Manager QC
Qualification: Bsc
Enrollment No. II-009545
Avadh University Ayodhya