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

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	Eptocan 250	**AR. No.**	NL/LA/FG/26/467
Generic Name	Phenytoin Sodium Injection USP		
Mother Batch No.	A26HE002	**Reference**	USP
Child Batch No.	A26HE002A	**Batch Size**	27450 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**	09/09/2026
Release Date	23/09/2026		

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	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	5.04 ml
4.	**Extractable Volume**	Not less than 5.0 ml	5.04 ml
5.	**pH (At 25°C ±2°C)**	10.0 to 12.3	11.07
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	497.0 particles/container
	(ii) Equal to or greater than 25µm	Not more than 600 particles /container	13.0 particles/container
7.	**Sterility**	Should comply the test of sterility	Complies

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	**Rahul Singh**	**Sunil Kumar**	**Aditya Singh**
Designation	**Sr.Officer QC**	**Executive QC**	**Manager QC**
Signature	Rahul		
Date	23/09/26	23/09/26	

Approved By
Name : Aditya Singh
Designation : Manager QC
Qualification : Bsc
Enrollment No. U-09345
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%	 9.2714% 38.8416%
10.	**Assay:** Each ml contains: Phenytoin Sodium IP 50 mg	47.50 mg to 52.50 mg (95.00% to 105.00%)	51.66 mg (103.32%)
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	**Rahul Singh**	**Sunil Kumar**	**Aditya Singh**
Designation	**Sr.Officer QC**	**Executive QC**	**Manager QC**
Signature	Rahul	23/09/26	Approved By Name : Aditya Singh Designation : Manager QC Qualification : B.Sc. Enrollment No. CPB-800545 Avadh University, Ayodhya
Date	23/09/26		23/09/26