

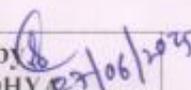
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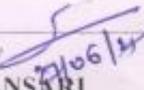
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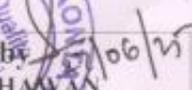
Certificate of Analysis Finished Product

Product Name	EPTOCAN Injection	A.R. No.	NL/FP/25/090
Generic Name	Phenytoin Sodium Injection USP 2ml	Sampled qty.	45 Ampoules
Batch No.	A25069H	Sampled by	Rakesh
Batch Size	59,950 Ampoules	Sampled on	11/06/2025
Mfg. Date	05/2025	Date of Testing	11/06/2025
Exp. Date	04/2027	Date of Release	27/06/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear colourless solution filled in amber glass ampoule.	A clear colourless solution filled in amber glass ampoule.
2.	Identification (By IR) (By HPLC)	A. Residue obtained from the sample meets the requirement, The absorption spectrum of the test preparation should exhibit maxima at same wavelength with that obtained with similar preparation of Phenytoin sodium working standard. B. 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.	Nominal fill volume	NLT 2ml	2.0 ml
4.	Container content for liquid	NLT Nominal volume.	2.1 ml
5.	pH	10.0 to 12.3	11.52
6.	Alcohol & Propylene glycol (by GC)		
	Alcohol	9.0% to 11.0%	9.05%
	Propylene glycol	37% to 43%	39.28%
7.	Particulate Matter (A.) Light Obscuration Particle Count Test 1. Particles $\geq 10 \mu\text{m}$ 2. Particles $\geq 25 \mu\text{m}$ (B.) Visible Particles	NMT 6000/Ampoule NMT 600/Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally.	141/Ampoule 2/Ampoule Complies
8.	Sterility	No microbial growth should be observed.	Complies
9.	Bacterial Endotoxins	NMT 0.3 USP EU/mg of Phenytoin Sodium.	Less than 0.3 USP EU/mg of Phenytoin Sodium.
10.	Assay: Each ml contains:		

Analysis by 
NAME: SANDHYA

Checked by 
NAME: SUFIYAN ANSARI

Approved by 
NAME: SWATI DHAMA



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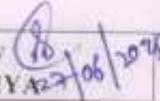
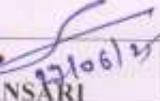
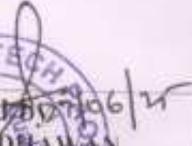
Surajpur, Paonta sahib Dist. Sirmour (H.P)

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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Phenytoin Sodium IP	50 mg	50.575 mg	101.15%	95.0% to 105.0%
Propylene Glycol IP	0.4 ml	0.3928 ml	39.28%	37% to 43%
Absolute Alcohol IP	0.1 ml	0.0905 ml	9.05%	9.0% to 11.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/not complies as per IP/BP/USP/US.

Analysis by  NAME: SANDHYA 27/06/2025
Checked by  NAME: SUFIYAN ANSARI 27/06/25
Approved by  NAME: SWATI BHAWAN 27/06/25

