

Title :

## Certificate of Analysis Finished Product

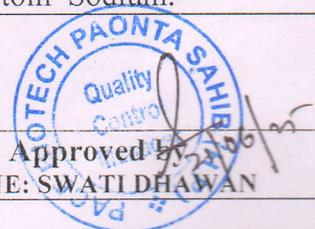
Product Name	Eptocan Injection	A.R. No.	NL/FP/25/082
Generic Name	Phenytoin Sodium Injection USP 2ml	Sampled qty.	45 Ampoules
Batch No.	A25006B	Sampled by	Aakash
Batch Size	1,00,000 Ampoules	Sampled on	05/06/2025
Mfg. Date	04/2025	Date of Testing	05/06/2025
Exp. Date	03/2027	Date of Release	21/06/2025

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	11.26
6.	Alcohol & Propylene Glycol content (by GC)		
	Alcohol	9.0% to 11%	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.	200/Ampoule 4/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: SWATIDHAWAN



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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Phenytoin Sodium I.P	50 mg	49.732 mg	99.46%	95.0% to 105.0%
Propylene Glycol I.P	0.4 ml	0.3928 ml	39.28%	37% to 43%
Absolute Alcohol I.P	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/HIS~~.



Analysis by NAME: SANDHYA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: SWATI DHAWAN
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