

Pace

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Pace Biotech

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

Certificate of Analysis Finished Product

Title	:		
Product Name	Eptocan 250 Injection	A.R. No.	NL/FP/24/389
Generic Name	Phenytoin Sodium Injection USP 5ml	Sampled qty.	45 Ampoules
Batch No.	A24224A	Sampled by	Boby Kumar
Batch Size	48,900 Ampoules	Sampled on	07/11/2024
Mfg. Date	09/2024	Date of Testing	07/11/2024
Exp. Date	08/2026	Date of Release	22/11/2024

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- 5ml	5.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	5.1 ml
5.	pH	10.0 to 12.3	11.12
6.	Alcohol & Propylene Glycol Content (by GC)		
	Alcohol	9 to 11%	9.78%v/v
	Propylene Glycol	37 to 43%	40.56%v/v
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.	137/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: SUFIYAN ANSARI

Checked by 
NAME: SANDHYA

Approved by
NAME: P. N. TRIPATHI



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Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Phenytoin Sodium I.P	50 mg	49.30 mg	98.60%	95.0% to 105.0%

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/AHS.



Analysis by NAME: SUFIYAN ANSARI	Checked by NAME: SANDHYA	Approved by NAME: P. N. TRIPATHI
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