

Pace

Add Pace To Health

Pace Biotech

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

Certificate of Analysis Finished Product

Title	:		
Product Name	Eptocan Injection	A.R. No.	NL/FP/24/166
Generic Name	Phenytoin Sodium Injection USP 2ml	Sampled qty.	45 Ampoules
Batch No.	A24090A	Sampled by	Vineet
Batch Size	43,100 Ampoules	Sampled on	14/06/2024
Mfg. Date	06/2024	Date of Testing	14/06/2024
Exp. Date	05/2026	Date of Conditionally Release	20/06/2024

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 exhibits 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.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml
5.	pH	10.0 to 12.3	11.42
6.	Alcohol & Propylene Glycol Content	Complies as per USP.	Under process
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.	22/Ampoule 1/Ampoule Complies
8.	Sterility	No microbial growth should be observed.	Under process
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:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Phenytoin Sodium I.P	50 mg	50.62 mg	101.24%	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/IHS.

Analysis by	Checked by	Approved by
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