

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	Eptocan Injection	A.R. No.	NL/FP/24/435
Generic Name	Phenytoin Sodium Injection USP 2ml	Sampled qty.	45 Ampoules
Batch No.	A24325C	Sampled by	Har Gyan Singh
Batch Size	1,00,000 Ampoules	Sampled on	12/12/2024
Mfg. Date	12/2024	Date of Testing	12/12/2024
Exp. Date	11/2026	Date of Release	27/12/2024

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	10.78
6.	Alcohol & Propylene Glycol Content (by GC)		
	Alcohol	9 to 11%	10.08%
	Propylene Glycol	37 to 43%	41.98%
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.	72/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: N. TRIBATHI



Pace

Add Pace To Health

Pace Biotech

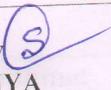
Surajpur, Paonta sahib Dist. Sirmour (H.P)

Certificate of Analysis Finished Product

Title		:	
Product Name	Eptocan Injection	A.R. No.	NL/FP/24/435
Generic Name	Phenytoin Sodium Injection USP 2ml	Sampled qty.	45 Ampoules
Batch No.	A24325C	Sampled by	Har Gyan Singh
Batch Size	1,00,000 Ampoules	Sampled on	12/12/2024
Mfg. Date	12/2024	Date of Testing	12/12/2024
Exp. Date	11/2026	Date of Release	27/12/2024

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Phenytoin Sodium I.P	50 mg	49.37 mg	98.74%	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/HS.

Analysis by  NAME: SANDHYA	Checked by  NAME: SUFIYAN ANSARI	 12/24
------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------