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Pace Biotech

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

Title	:	Certificate of Analysis Finished Product

Product Name	**Eptocan** Injection	**A.R. No.**	NL/FP/24/293
Generic Name	Phenytoin Sodium Injection USP 100mg/2ml	**Sampled qty.**	45 Ampoules
Batch No.	A24181C	**Sampled by**	Aakash
Batch Size	1,00,000 Ampoules	**Sampled on**	05/09/2024
Mfg. Date	08/2024	**Date of Testing**	05/09/2024
Exp. Date	07/2026	**Date of Release**	20/09/2024

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)	**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.	Complies
	(By HPLC)	**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
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 to12.3	11.12
6.	Alcohal & Propylene Glycol Content (by GC)		
	Alcohol	9 to 11%	10.23%
	Propylene Glycol	37 to 43%	37.58%
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	NMT-6000/Ampoule NMT-600/Ampoule	31/Ampoule 1/Ampoule
	(B.) Visible Particles	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally.	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	Checked by	Approved by

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager

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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/~~IHS~~.

Analysis by	Checked by	Approved by

PACE BIOTECH PAONTA SAHIB (H.P.) Quality Control Manager