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Pace Biotech

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

Title : Certificate of Analysis Finished Product

Product Name	**Eptocan 250** Injection	**A.R. No.**	NL/FP/25/091
Generic Name	Phenytoin Sodium Injection USP 5ml	**Sampled qty.**	45 Ampoules
Batch No.	A25010A	**Sampled by**	Rakesh
Batch Size	30,000 Ampoules	**Sampled on**	11/06/2025
Mfg. Date	04/2025	**Date of Testing**	11/06/2025
Exp. Date	03/2027	**Date of Release**	27/06/2025

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)	**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 5ml	5.0 ml
4.	Container content for liquid	NLT Nominal volume.	5.1 ml
5.	pH	10.0 to12.3	11.57
6.	Alcohal & Propylene Glycol Content (by GC)		
	Alcohol	9.0% to 11%	9.06%
	Propylene Glycol	37% to 43%	39.26%
7.	Particulate Matter		
	(A.) Light Obscuration Particle Count Test 1.Particles ≥10 µm 2.Particles ≥25 µm	NMT-6000/Ampoule NMT-600/Ampoule	377/Ampoule 7/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
NAME: SANDHYA 27/06/2025	NAME: SUFIYAN ANSARI 27/06/25	NAME: SWATI DHAWAN 27/06/25

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	IP	50 mg	50.627 mg	101.25%	95.0% to 105.0%
Propylene Glycol	IP	0.4 ml	0.3926 ml	39.26%	37% to 43%
Absolute Alcohol	IP	0.1 ml	0.0906 ml	9.06%	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/~~IHS~~.

PACE BIOTECH PAONTA SAHIB
Quality Control Manager

Analysis by	Checked by	Approved by
27/06/2025	27/06/25	27/06/25
NAME: SANDHYA	NAME: SUFIYAN ANSARI	NAME: SWATI DHAWAN