



AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

Title : Certificate of Analysis Finished Product

Product Name	EPTOCAN Injection	A.R. No.	ARN/FP/26/080
Generic Name	Phenytoin Sodium Injection 5ml	Sampled qty.	45 Ampoules
Batch No.	ARN2669A	Sampled by	Shivanand
Batch Size	48,700 Ampoules	Sampled on	06/09/2026
Mfg. Date	08/2026	Date of Testing	07/09/2026
Exp. Date	07/2028	Date of Release	21/09/2026

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 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	11.28
6.	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.	242/Ampoule 57/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins (IHS)	NMT 0.3 EU/mg of Phenytoin Sodium.	Less than 0.3 EU/mg of Phenytoin Sodium.
9.	Assay: Each ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Phenytoin Sodium IP	50 mg	49.59660 mg	99.19%	90.0% to 110.0%

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 11/09/26
NAME: FIROJ KHAN

Checked by 11/09/26
NAME: SURJEET KAUR

Name : Mrs. Swati Dhawan
Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
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