

**AMERICAN REMEDIES HEALTHCARE PVT. LTD.**

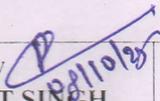
Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

**Title : Certificate of Analysis Finished Product**

<b>Product Name</b>	EPTOCAN Injection	<b>A.R. No.</b>	ARN/FP/25/024
<b>Generic Name</b>	Phenytoin Sodium Injection 2ml	<b>Sampled qty.</b>	45 Ampoules
<b>Batch No.</b>	ARN2514A	<b>Sampled by</b>	Anuj Verma
<b>Batch Size</b>	99,300 Ampoules	<b>Sampled on</b>	23/09/2025
<b>Mfg. Date</b>	08/2025	<b>Date of Testing</b>	23/09/2025
<b>Exp. Date</b>	07/2027	<b>Date of Release</b>	08/10/2025

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)  (By HPLC)	<b>A.</b> 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>B.</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	11.13		
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.	143.07/Ampoule 34.13/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	49.023 mg	98.05%	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   
NAME: RAMANJEET SINGHChecked by   
NAME: SUFIYAN ANSARIApproved by   
NAME: MRS. SWATI DHANWAN