



# 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/26/078 |
| Generic Name | Phenytoin Sodium Injection 2ml | Sampled qty.    | 45 Ampoules   |
| Batch No.    | ARN2667A                       | Sampled by      | Shivanand     |
| Batch Size   | 99,100 Ampoules                | Sampled on      | 05/09/2026    |
| Mfg. Date    | 08/2026                        | Date of Testing | 06/09/2026    |
| 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)<br><br>(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.<br>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<br><br>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                                                                                                                                                                                                                                                                                                                                                                    | 11.30                                                      |
| 6.     | Particulate Matter<br>(A) Light Obscuration Particle Count Test<br>1. Particles $\geq 10 \mu m$<br>2. Particles $\geq 25 \mu m$<br>(B) Visible Particles | NMT 6000/Ampoule<br>NMT 600/Ampoule<br>The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally.                                                                                                                                                                                                           | 76/Ampoule<br>3/Ampoule<br>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:<br>Each ml contains:                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                 |                                                            |

| Ingredients         | Labeled Claim | Found       | % of labeled amount | Limits % of labeled amount |
|---------------------|---------------|-------------|---------------------|----------------------------|
| Phenytoin Sodium IP | 50 mg         | 50.87416 mg | 101.75%             | 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 ✓

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