

Pace

Add Pace To Health

Pace Biotech

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

Title

Certificate of Analysis Finished Product

| | | | |
|--------------|---|-----------------|--------------|
| Product Name | MENACAN K-3 Injection | A.R. No. | NL/FP/25/221 |
| Generic Name | Menadione Sodium Bisulphate Injection 1ml | Sampled qty. | 45 Ampoules |
| Batch No. | A25177A | Sampled by | Aakashdeep |
| Batch Size | 1,00,000 Ampoules | Sampled on | 18/10/2025 |
| Mfg. Date | 08/2025 | Date of Testing | 18/10/2025 |
| Exp. Date | 07/2027 | Date of Release | 06/11/2025 |

| S. No. | Tests | Specifications | Observations | | |
|--|--|--|---|----------------------|-----------------------------|
| 1. | Description | A yellowish colour solution filled in amber colour glass ampoule. | A yellowish colour solution filled in amber colour glass ampoule. | | |
| 2. | Identification (By HPLC) | In the Assay, the principal peak in the chromatogram obtained with the test solution corresponding to the peak in the chromatogram obtained with the reference solution. | Complies | | |
| 3. | Nominal fill volume | NLT 1ml | 1.0 ml | | |
| 4. | Extractable Volume | NLT Nominal volume or NMT 110% of Nominal volume. | 1.1 ml | | |
| 5. | pH (IHS) | 4.0 to 6.0 | 4.59 | | |
| 6. | Particulate Matter | | | | |
| | (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ | NMT 6000/Ampoule NMT 600/ Ampoule | 7/Ampoule 0/Ampoule | | |
| | (B.) Visual Particle | The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eyes. | Complies | | |
| 7. | Sterility | No microbial growth should be observed. | Complies | | |
| 8. | Bacterial Endotoxins (IHS) | NLT 5.83 EU/mg. | Less than 5.83 EU/mg. | | |
| 9. | Assay: (By HPLC) Each ml contains: | | | | |
| Ingredients | | Labelled Claim | Found | % of labelled amount | Limits % of labelled amount |
| Menadione Sodium Bisulphate Eq. to 5.2mg pf Menadione | | 10 mg | 9.5482 mg | 95.48% | NLT 90.0% |

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.

Name : Mrs. Swati Dhawan

Designation : QC HOD

Qualification : M.Sc. Clinical Microbiology

Registration No. : 5924000000

Analysis by

NAME: RAMANJEET SINGH

Checked by

NAME: NIKHIL SINGH