

**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>	MENACAN K3 Injection	<b>A.R. No.</b>	ARN/FP/25/042
<b>Generic Name</b>	Menadione Sodium Bisulphate Injection 1ml	<b>Sampled qty.</b>	45 Ampoules
<b>Batch No.</b>	ARN2511A	<b>Sampled by</b>	Rakesh
<b>Batch Size</b>	99,500 Ampoules	<b>Sampled on</b>	23/10/2025
<b>Mfg. Date</b>	08/2025	<b>Date of Testing</b>	23/10/2025
<b>Exp. Date</b>	07/2027	<b>Date of Release</b>	07/11/2025

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	4.60
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$  (B.) Visual Particle	NMT 6000/Ampoule NMT 600/ Ampoule  The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eyes.	34/Ampoule 1/Ampoule  Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins (IHS)	NMT 5.83EU/mg.	Less than 5.83EU/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 of Menadione	10 mg	9.6430 mg	96.43%	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.

Analysis by  
NAME: RAMANJEET SINGHChecked by  
NAME: NIKHIL SHARMAApproved by  
NAME: MRS. SWATHI DEVI