


Title : Certificate of Analysis Finished Product

Product Name	MENACAN -K3 Injection	A.R. No.	ARN/FP/26/009
Generic Name	Menadione Sodium Bisulphate Injection 1ml	Sampled qty.	60 Ampoules
Batch No.	ARN25116A	Sampled by	Rakesh
Batch Size	3,00,000 Ampoules	Sampled on	05/05/2026
Mfg. Date	03/2026	Date of Testing	06/05/2026
Exp. Date	02/2028	Date of Release	21/05/2026

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	4.50
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.	8/Ampoule 1/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins (IHS)	NMT 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 of Menadione	10 mg	10.46686 mg	104.67%	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: FIROJ KHAN	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: MRS. SWATI DHAWAN
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