



Tamman Titoe Pharma Pvt Ltd
56-57, Sidco Pharmaceutical Complex,
Alathur-603 110, Tamilnadu.

QUALITY CONTROL DEPARTMENT
Certificate of Analysis of Finished Product
(Under Drug And Cosmetic Act. 1940 & The Rules There Under)

Report No: TT/ FG/735/23-24
Report Date: 07-04-2024

Name of the product : MENACAN K3 Injection 1ml
Generic Name : Menadione Sodium Bisulphite Injection I.P "66(Vitamin K Analogue)
Batch No. : VK404
Batch Size : 107000
Mfg. Date. : Mar-2024
Exp. Date. : Feb-2026
Quantity of Sample : 100 Nos
Date of Sampling : 23-03-2024
Date of Commencement of analysis : 23-03-2024
Date of Completion of analysis : 06-04-2024

TEST NAME	SPECIFICATION	OBSERVATION
Description	A clear, colourless solution.	A clear, colourless solution
Identification:		
Melting Range :	104 ° to 107°	Complies to IP specification
B. Warm 2ml of 4%w/v solution with few drops of dilute Hcl	Sulphur dioxide is evolved.	Complies to IP specification
pH	2.0 to 4.0	3.37
Extractable Volume	NLT- 1.0ml/Ampoule	1.1 ml
Particulate matter	No visible particles	No visible particles
Sterility Test	To comply as per IP	Comply as per IP
Assay: Each ml contains : Menadione sodium Bisulphite I.P "66 10mg Equivalent.to 5.2 mg of Menadione.	4.68mg to 5.72 mg (90.0. % - 110.0%)	5. 25mg (105.00%)

OBSERVATION: In the opinion of the undersigned the sample referred to above is of ~~Standard~~ ☒ ~~Not Standard~~ Quality as in the act and the rules made there under for the reason given below.

REMARKS : COMPLIES AS PER IP "66/ IHS WITH RESPECT TO THE ABOVE TESTS ONLY CARRIED OUT.

Analysed By: V. B. J.
Date: 07/04/24

Checked By:
Date: 07/04/24

Person In Charge of Testing
Date:

