

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/671/23-24 Report Date: 04-03-2024

Name of the product

:MENACAN K3 Injection 1ml

Generic Name

: Menadione Sodium Bisulphite Injection I.P "66(Vitamin K Analogue)

Batch No. Batch Size

: VK403

Mfg. Date.

:158000

Exp. Date.

: Feb-2024 : Jan-2026

Quantity of Sample Date of Sampling

:100 Nos

Date of Commencement of analysis

:18-02-2024

Date of Completion of analysis

:18-02-2024 : 03-03-2024

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	3.87
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:	4.68mg to5.72 mg	5. 31mg
Each ml contains: Menadione sodium Bisulphite I.P "66 10mg Equivalent.to 5.2 mg of Menadione.	(90.0. % - 110.0%)	(106.20%)

In the opinion of the undersigned the sample referred to above is of Standard Quality/Not-Standard Quality as OBSERVATION:

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 CARRIEDOUT.

Checked By: Date:

rge of Testing