

Title : Certificate of Analysis Finished Product

Product Name	KDION 1 Injection	A.R. No.	NL/FP/25/107
Generic Name	Phytomenadione Injection IP 1mg/0.5ml	Sampled qty.	60 Ampoules
Batch No.	A25125A	Sampled by	Rakesh
Batch Size	75,000 Ampoules	Sampled on	28/06/2025
Mfg. Date	06/2025	Date of Testing	28/06/2025
Exp. Date	05/2027	Date of Release	13/07/2025

S. No.	Tests	Specifications	Observations
1.	Description	A clear to slightly opalescent pale yellow or yellow coloured liquid filled in amber colour ampoule.	A clear yellow coloured liquid filled in amber colour ampoule.
2.	Identification	A. When Examined in the range 230nm to 350nm, a 0.01%w/v solution in ethanol shows absorption maxima at 328 nm and Minima at 292 nm. B. When examined in the range 230nm to 350nm, a 0.001% w/v solution in ethanol shows absorption maxima at 245, 249, 263and 271nm and Minima at 256nm and 266 nm.	Complies Complies
3.	Nominal fill volume	NLT 1 ml	1.0 ml
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	1.1 ml
5.	pH	5.0 to 7.5	5.67
6.	Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual	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 observed on visual inspection.	6/Ampoule 0/Ampoule Complies
7.	Sterility	No microbial growth should be observed.	Complies
8.	Bacterial Endotoxins	NMT 14.0 EU/mg.	Less than 14.0 EU/mg.
9.	Assay: Each 0.5ml contains:		

Ingredients	Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Phytomenadione IP	1 mg	0.9886 mg	98.86%	90.0% to 115.0%

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/HS.

Analysis by NAME: SANDHYA	Checked by NAME: SUFIYAN ANSARI	Approved by NAME: SWATI DHAWAN
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