

Title

Certificate of Analysis Finished Product

Product Name	KDION 1 Injection	A.R. No.	NL/FP/24/158
Generic Name	Phytomenadione Injection IP 1mg/0.5ml	Sampled qty.	60 Ampoules
Batch No.	A24099D	Sampled by	Aakashdeep
Batch Size	14,900 Ampoules	Sampled on	11/06/2024
Mfg. Date	06/2024	Date of Testing	11/06/2024
Exp. Date	05/2026	Date of Release	26/06/2024

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	<p>A. When Examined in the range 230nm to 350nm, a 0.01% w/v solution in ethanol. Shows absorbance maxima at 238 nm and Minima at 292 nm.</p> <p>B. When Examined in the range 230nm to 350nm, a 0.01% w/v solution in ethanol. Shows absorbance maxima at 245, 248, 263 nm and Minima at 256nm and 266nm.</p>	Complies Complies		
3.	Nominal fill volume	NLT- 0.5 ml	0.5 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	0.5 ml		
5.	pH	5.0 to 7.5	6.70		
6.	Particulate Matter	<p>(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$</p> <p>(b.) Visual</p>	<p>5/Ampoule 1/Ampoule</p> <p>Complies</p>		
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$			NMT-6000/Ampoule NMT-600/Ampoule	
	(b.) Visual			The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles unintentionally.	
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	0.9831 mg	98.31%	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

Checked by

Approved by

