



# Pacebiotech Pharma (India) Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

## CERTIFICATE OF FINISH PRODUCT ANALYSIS

<b>Product Name:</b>	Kdion 10 Injection (Phytomenadione Injection 10 mg/ml)		
<b>Batch No.</b>	25AE072A	<b>A.R. No.</b>	PV250453
<b>Batch Size</b>	30100 Ampoules	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	05/2025	<b>Date of Testing</b>	17/05/2025
<b>Exp. Date</b>	04/2027	<b>Date of Release</b>	04/06/2025
<b>Reference Batch No</b>	25AE072	<b>MFG. Lic. No.</b>	N-MB-2023/263

Sr. No.	Test	Specification	Observation
1.	Description	A clear to slightly opalescent pale yellow coloured liquid, when maintained at a temperature below 25°.	A clear to slightly opalescent pale yellow coloured liquid, when maintained at a temperature below 25°.
2.	Identification	A. When examined in the range 230 nm to 350 nm (2.4.7), a 0.01 per cent w/v solution in ethanol shows absorption maxima at 288 nm and minima at 292 nm. B. When examined in the range 230 nm to 350 nm (2.4.7), a 0.001 per cent w/v solution in ethanol shows absorption maxima at 245, 249, 263 and 271 nm and minima at 256 nm and 266 nm.	Complies
3.	pH	Between 5.0 to 7.5	6.83
4.	Extractable Volume	NLT 1.0 ml	1.0 ml
5.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
6.	Bacterial Endotoxins	NMT 14.0 EU/mg	Less than 14.0 EU/mg
7.	Sterility	Should be complies	Sterile



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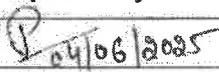
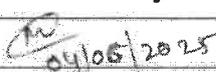
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Assay:			
8.	Each ml contains Phytomenadione IP 10mg	90.0 to 115.0 % (9 mg to 15 mg)	98.11% (9.81 mg)

Remark: The sample is complies as per <sup>IP</sup>/BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 04/06/2025	 04/06/2025	 04/06/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC