



DERREN HEALTHCARE PRIVATE LIMITED

PLOT NO 33,35/P & 36/P, XCELON INDUSTRIAL PARK,
SARKHEJ-BAVLA HIGHWAY, VILL. VASNA - CHACHARWADI,
TA : SANAND. DIST.AHMEDABAD - 382213, GUJARAT,INDIA

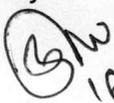
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FINISHED PRODUCT ANALYTICAL TEST REPORT

Product Name	PROTACAN	Specification No.	DHPL/FP/SPEC/PROTA/01/00
Generic Name	PROTAMINE SULPHATE INJECTION IP	Batch No. /Lot No.	CA25003
		Mfg. Dt.	06/2025
		Exp. Dt.	05/2027
		Receipt Dt.	28/06/2025
		Release Dt.	16/07/2025
		Sample Size	41.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/25/0145
		Manufactured By	DERREN
Analysis	DHIREN MUKESHBHAI PATEL	Theoretical Yield/Batch Size	11,538.000 Ampoule

Sr.	Test	Limit	Result
1	Description	Clear, colourless or Almost colourless solution free from Visible particles and fibers	Clear, colourless solution free from Visible particles and fibers
2	Extractable volume	NLT 5.0 ml	5.0 ml
3	pH	2.5 to 3.5	3.0
4	Identification	.	.
	Identification A by Chemical test	Red Color is Produced	Red Color is Produced
	Identification B by chemical test	A White Precipitated is Formed	A White Precipitated is Formed
5	Specific optical rotation	-0.68° To -0.52°	-0.63°
6	Light absorption	NMT 0.1 %	0.01 %
7	Bacterial endotoxins	NMT 7.0 EU/mg	Less than 7.0 EU/mg
8	Particulate matter	.	.
	By Visual inspection	The solution should be free from particles that can be observed by inspection with the unaided eye.	The solution free from particles that can be observed by inspection with the unaided eye.
	By light obscuration method	Sub visible particle by LPC >10 microns=NMT 6000/Container > 25 Microns=NMT 600/Container	Sub visible particle by LPC >10 microns=68.33/Container > 25 Microns=0.33/Container

Conclusion : In the opinion of undersigned the sample referred to above is standard quality as per IP specification.

Prepared By  16/07/25	Checked By  16/07/25	Approved By  16/07/25
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Analysis	DHIREN MUKESHBHAI PATEL	Manufactured By	DERREN
		Theoretical Yield/Batch Size	11,538.000 Ampoule

Sr.	Test	Limit	Result
9	Sterility test	Should be sterile	sterile
10	Abnormal toxicity	Complies with the test for abnormal toxicity	Complies with IP test in mice using a dose of 0.5 mg/0.5 ml/mouse IV
11	Assay Assay Each ml Contains:ProtamineSulphate 10.0mg/ml	Not less than 80 % IU/mg of the amount of Protamine sulphate injection	130.70 IU/mg of the amount of Protamine sulphate injection

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Prepared By  16/07/25	Checked By  16/07/25	Approved By  16/07/25
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