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

FINISHED PRODUCT ANALYTICAL TEST REPORT

Product Name	**PROTACAN**	**Specification No.**	DHPL/FP/SPEC/PROTA/01/02
Generic Name	PROTAMINE SULPHATE INJECTION IP	**Batch No. /Lot No.**	CA26008
		Mfg. Dt.	09/2026
		Exp. Dt.	08/2028
		Receipt Dt.	12/09/2026
		Release Dt.	03/10/2026
		Sample Size	35.000 Ampoule
		Mfg. Lic. No.	G/28/1862
		A.R. No.	FP/26/0339
		Manufactured By	DERREN
Analysis	KRUNAL HARMATSINH CHAVDA	**Theoretical Yield/Batch Size**	16,346.000 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	5.1 ml
3	pH	2.5 to 3.5	3.23
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°	-0.6094°
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 is 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= 18.00/Container > 25 Microns= 0.00/Container

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

Prepared By	Checked By	Approved By
03/10/26	03/10/26	03/10/26

DERREN HEALTHCARE PVT. LTD. QUALITY ASSURANCE AHMEDABAD

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		A.R. No.	FP/26/0339
Analysis	KRUNAL HARMATSINH CHAVDA	**Manufactured By**	DERREN
		Theoretical Yield/Batch Size	16,346.000 Ampoule

Sr.	Test	Limit	Result
9	Sterility test	Should be sterile	sterile
10	Abnormal toxicity	Complies with the test for abnormal toxicity	Complies with the test for abnormal toxicity
11	Assay Assay Each ml Contains:ProtamineSulphate 10.0mg/ml	Not less than 80 % IU/mg of the amount of Protamine sulphate injection	130.6 % IU/mg of the amount of Protamine sulphate injection

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

Prepared By	Checked By	Approved By
03/10/26	03/10/26	DERREN HEALTHCARE PVT. LTD. QUALITY ASSURANCE 03/10/26