

**DERREN HEALTHCARE PVT. LTD.**

Plot No. #33, 35/p & 36/p XCELON Industrial Park, Lane besides Chak-de-India
Weighbridge, Sarkhej-Bavla Highway Village: Vasna-Chacharvadi,
Ahmedabad-382 213, Gujarat (India)

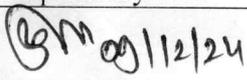
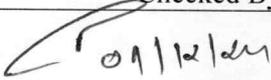
**CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)**

Name of Product	Protamine Sulphate injection IP 10 mg /ml (PROTACAN)		
Batch No.	CA24003	A.R. No.	FP/24/0133
Mfg. Date	11/24	Exp. Date	10/26
Sampled Qty.	41 Nos.	Date of Analysis	17/11/24
Batch Size	60 Ltr.	Date of Release	09/12/24
Container Type	Amber Glass Ampoule	Fill Volume	5.0 ml
Mfg. Lic. No.	G/28/1862		

Sr. No.	Test	Result	Specification
1	Description	Clear, colourless liquid free from visible particles and fibers.	Clear, colourless or almost colourless liquid free from visible particles and fibers.
2	Extractable volume	5.2 ml	NLT 5.0 ml
3	pH	3.22	2.5 to 3.5
4	Identification		
4.1	Identification A by Chemical Test	Red Color is Produced	Red Color is Produced
4.2	Identification B by Chemical Test	A White Precipitated is Formed	A White Precipitated is Formed
5	Specific Optical rotation	- 0.55°	-0.68° To -0.52°
6	Light Absorption	Less than 0.1%	NMT 0.1 %
7	Bacterial endotoxin	Less 7.0 EU/mg of Protamine Sulphate	NMT 7.0 EU/mg of Protamine Sulphate
8	Particulate matter		
8.1	By Visual Inspection	The solution is free from particles that is observed by inspection with the unaided eye.	The solution should be free from particles that can be observed by inspection with the unaided eye.
8.2	By Light Obscuration Method	≥10 microns = 21.00/Container ≥25 Microns = 15.67/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
9	Sterility test	Sterile	Should be sterile
10	Abnormal toxicity	Complies	Complies with IP test in mice using a dose
11	Assay		
11.1	Each ml Contains: Protamine Sulphate eq. to Protamine Sulphate 10mg	128.9 IU/mg of the labeled amount of Protamine Sulphate	Not less than 80IU/mg the labeled amount of Protamine Sulphate

Conclusion: The above sample complies as per IP specification.

In the opinion of the undersigned the sample referred to above is **of standard / not of standard** quality as defined in the act and the rules made there under for the reasons given above.

Prepared By  QC Executive	Checked By  QC Sr. Executive	Approved By  QA MANAGER
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