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	Tranexamic Acid Injection IP 500mg/5 ml (TRANEXACAN)		
Batch No.	AC24003	**A.R. No.**	FP/24/0038
Mfg. Date	05/24	**Exp. Date**	04/26
Sampled Qty.	81 Nos.	**Date of Analysis**	16/05/24
Batch Size	300 Ltr.	**Date of Release**	31/05/24
Container Type	Clear 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 to slightly yellowish liquid free from visible particles and fibers.
2	Extractable volume	5.0 ml	NLT 5.0 ml
3	Identification		
3.1	Identification A by IR	The infrared absorption spectrum of the test preparation is concordant with the reference spectrum of the tranexamic acid WS.	The infrared absorption spectrum of the test preparation should be concordant with the reference spectrum of the tranexamic acid RS/WS.
3.2	Identification B by Chemical	A dark bluish violate colour is produced	A dark bluish violate colour should be produced
4	pH	7.5	6.5 to 8.0
5	Related substances		
5.1	Impurity A	Not detected	NMT 1.0%
5.2	Impurity B	0.37%	NMT 0.5%
5.3	Impurity C	Not detected	NMT 0.1%
5.4	Impurity D	Not detected	NMT 0.1%
5.5	Unspecified Impurity	Not detected	NMT 0.1%
6	Bacterial endotoxin	Less than 35 IU/ml	NMT 35 IU/ml
7	Particulate matter		
7.1	By Visual Inspection	The solution is free from particles of the foreign matter that can be observed on visual inspection method.	The solution should be free from particles of the foreign matter that can be observed on visual inspection method.
7.2	By Light Obscuration Method	≥10 microns= 186.67/Container ≥ 25 Microns= 3.67/Container	Sub visible particle by LPC ≥10 microns=NMT 6000/Container ≥ 25 Microns=NMT 600/Container
8	Sterility test	Sterile	Should be sterile
9	Assay		
9.1	Each ml Contains: Tranexamic acid IP 100 mg	99.1 % of the labeled amount	95.0% to 105.0% of the Labeled amount

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	Checked By	Approved By
NKPatel.	01/06/24	QUALITY ASSURANCE 01/06/24
QC OFFICER	QC EXECUTIVE	QA MANAGER