



American Remedies Healthcare Pvt. Ltd.

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

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Tranexacan Injection (Tranexamic Acid Injection IP 500 mg/5ml)		
Batch No.	25AR021	A.R. No.	AFP250013
Batch Size	150100 Amps	Sample Quantity	60 Nos
Mfg. Date	09/2025	Date of Testing	19/09/2025
Exp. Date	08/2027	Date of Release	06/10/2025
Reference Batch No	25AR021	MFG. Lic. No.	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	Description	A clear, colourless to yellowish liquid.	Clear and colorless liquid.
2.	Identification	A. On the residue, determine by infrared absorption spectrophotometry Compare the spectrum with that obtained with tranexamic acid IPRS or with the reference spectrum of tranexamic acid. B. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.	Complies
3.	Related substance	Should be complies	Complies
4.	pH	6.5 to 8.0	7.70
5.	Extractable Volume	NLT 5.0 ml	5 ml
6.	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
7.	Bacterial Endotoxins	NMT 0.5 EU/mg	Less than 0.5 EU/mg



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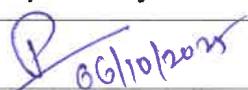
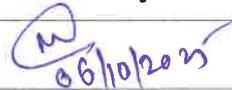
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8.	Sterility	Should be complies	Sterile
9.	Assay: Each 5ml contains Tranexamic Acid IP 500mg	(450.0 to 550.0mg) 90.0 to 110.0 %	(505.30 mg) 101.06 %

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

	Prepared By	Checked By	Approved By
Sign/Date	 06/10/2025	 06/10/2025	 06/10/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

