CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Product Name : **TRANEXAMIC ACID Injection 1 g/10 mL**	
Active Ingredient : Tranexamic acid	Analysis No. : QIF17-091301
Batch No. : E909F706	Analysis Date : September 27, 2017
Batch Size : 25,000 Ampules	Mfg. Date : August 10, 2017
Reference : BP 2017	Exp. Date : August 09, 2020

TESTS	*SPECIFICATIONS*	*RESULTS*
Description	Colorless and transparent solution, free of strange particles in a colorless ampule	Colorless and transparent solution, free of strange particles in a colorless ampule
Identification		
A. By IR	The IR absorption spectrums of the test specimen and the standard specimen exhibit maxima at the same wavelengths	Meets the requirements
B. By Test B	A dark-bluish violet colour is produced	Meets the requirements
C. By Test C	Melting Point : About 186°	186°
pH	Between 6.5 and 8.0	6.7
Related Substances		
Impurity A	Not more than 1%	0.0%
Impurity B	Not more than 0.5%	0.0%
Impurity C	Not more than 0.1%	0.0%
Impurity D	Not more than 0.1%	0.0%
Any Other Impurity	Not more than 0.1%	0.0%
Bacterial Endotoxins	Not more than 35 IU per mL	Not more than 35 IU per mL
Sterility	Sterile	Sterile
Foreign Matter	Not detected	Not detected
Particulate Matter	Not more than 6000 per ampule (≥ 10 μm) Not more than 600 per ampule (≥ 25 μm)	25/Ampule 1/Ampule
Airtightness	No leak	No leak
Volume Variation	Not less than the labeled volume (10 mL) in the case of containers examined individually	10.5 mL
Assay	Between 95.0% and 105.0%	98.2%

Remarks : Sample conforms to specifications.

KOREA UNITED PHARM, INC.
QUALITY CONTROL DEPT.

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QC/QA Director