IN-USE STABILITY STUDIES

TRANEXAMIC ACID INJECTION 1000 mg/10 mL

(Tranexamic acid)

KOREA UNITED PHARM. INC.

1. PROTOCOL

1.1. Product Name : TRANEXAMIC ACID INJECTION 1000 mg/10 mL

1.2. Active Ingredient : Tranexamic acid

1.3. Analysis Date : December 28, 2017 ~ December 29, 2017

1.4. Method of Reconstitution : TRANEXAMIC ACID may be mixed with 0.9% Sodium chloride solution and 5% Glucose solution to achieve final concentrations of 1 g in 100 mLs (10 mg/mL, 1%).

1.5. Test Products

Batch No.	Mfg. Date	Exp. Date	Batch Size
909F704	July 24, 2017	July 23, 2017	25,000 Ampules
909F705	August 09, 2017	August 08, 2017	25,000 Ampules
909F706	August 10, 2017	August 09, 2017	25,000 Ampules

1.6. Test Parameters

Test	Requirements
Description	Visual Inspection
pH	Between 6.5 and 8.0
Assay	Between 95.0 and 105.0%

1.7. Test Conditions

Diluents	Conditions	Concentration
0.9% Sodium chloride solution	For 24 hours at 2 ~ 8℃	10 mg/mL
5% Glucose solution	For 24 hours at 2 ~ 8℃	10 mg/mL

1.8. Test Plans

Conditions	Sampling Intervals (hours)
0.9% Sodium chloride solution for 24 hours at 2 ~ 8℃	Initial, 12, 24
5% Glucose solution for 24 hours at 2 ~ 8℃	Initial, 12, 24

2. RESULT

2.1. 0.9% Sodium chloride solution

2.1.1. Batch No. 909F704

Test	Specification	Initial	12 hours	24 hours
Description	Colorless and transparent soution, free of strange particles in a colorless ampule	Conforms	Conforms	Conforms
pH	Between 6.5 and 8.0	6.80	6.89	6.81
Assay	Between 95.0 and 105.0%	97.67	97.67	98.89

2.1.2. Batch No. 909F705

Test	Specification	Initial	12 hours	24 hours
Description	Colorless and transparent soution, free of strange particles in a colorless ampule	Conforms	Conforms	Conforms
pH	Between 6.5 and 8.0	6.72	6.86	6.81
Assay	Between 95.0 and 105.0%	98.74	99.34	99.54

2.1.3. Batch No. 909F706

Test	Specification	Initial	12 hours	24 hours
Description	Colorless and transparent soution, free of strange particles in a colorless ampule	Conforms	Conforms	Conforms
pH	Between 6.5 and 8.0	6.78	6.89	6.74
Assay	Between 95.0 and 105.0%	98.30	98.16	97.82

2.2. 5% Glucose solution

2.2.1. Batch No. 909F704

Test	Specification	Initial	12 hours	24 hours
Description	Colorless and transparent soution, free of strange particles in a colorless ampule	Conforms	Conforms	Conforms
pH	Between 6.5 and 8.0	6.95	7.02	6.99
Assay	Between 95.0 and 105.0%	99.54	98.18	97.21

2.2.2. Batch No. 909F705

Test	Specification	Initial	12 hours	24 hours
Description	Colorless and transparent soution, free of strange particles in a colorless ampule	Conforms	Conforms	Conforms
pH	Between 6.5 and 8.0	6.92	6.99	6.79
Assay	Between 95.0 and 105.0%	99.98	97.52	98.09

2.2.3. Batch No. 909F706

Test	Specification	Initial	12 hours	24 hours
Description	Colorless and transparent soution, free of strange particles in a colorless ampule	Conforms	Conforms	Conforms
pH	Between 6.5 and 8.0	6.97	6.99	6.92
Assay	Between 95.0 and 105.0%	99.47	100.48	97.97

3. CONCLUSION

TRANEXAMIC ACID Injection 1000 mg/10 mL was diluted with 0.9% Sodium chloride solution and 5% Glucose solution was stable for up to 24 hours when stored at 2 ~ 8℃. Therefore, the in-use stability of TRANEXAMIC ACID Injection 1000 mg/10 mL is guaranteed for the periods under the conditions.

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