Impurities test for Tranexamic Acid (EP method)

SAMPLE PREPARATION:

Test Solution: Dissolve 0.2 g of Tranexamic acid in water and dilute to 20 mL with same solvent.

Reference solution-a: Dilute 5 mL of test solution in 100 mL water, dilute 1 mL of this solution to 10 mL with water.

Reference solution-b: Dissolve 20 mg of Tranexamic acid (containing impurity C) in water and dilute to 2 mL with same solvent.

Reference solution-c: Dissolve 12 mg of Impurity D in water and dilute to 100 mL with same solvent, dilute 1 mL of this solution to 50 mL with water. Dilute 5 mL of this solution to 200 mL with water.

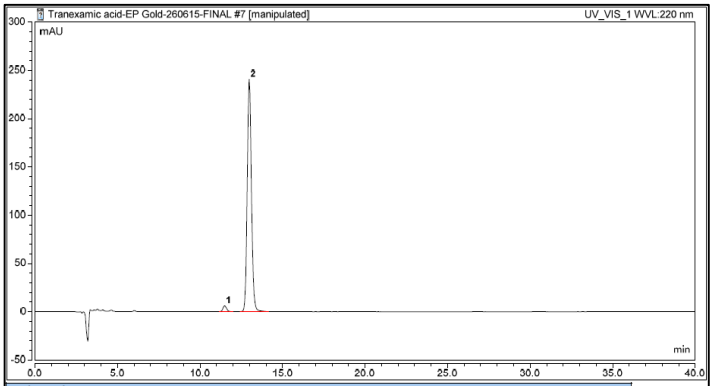
CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC
Column: Hypersil GOLD (4.6*250mm, 5 um, p/n 25005-254630, lot no.:13285)
Mobile phase A: Dissolve 11 g of anhydrous sodium dihydrogen phosphate in 500 mL water and add 5 mL of triethylamine and 1.4 g of sodium lauryl sulfate. Adjust to pH 2.5 with OPA and dilute to 600 mL with water. Add 400 mL of methanol
Separation Mode: Isocratic
Column temperature: 25˚C
Flow rate: 0.9 mL/min
Injection Volume: 20 µL
Detector wavelength: UV 220nm
Run Time: 40 min

System Suitability Results:

Sr. No.	Parameters	EP Criteria	Obtained Results
1	Resolution between Tranexamic acid & impurity-C in reference solution (b)	Minimum 1.5	3.48
2	RRT of Impurity C, D and B with reference to Tranexamic acid	Impurity-C= about 1.1min Impurity-D= about 1.3 min Impurity-B= about 1.5 min	Imp-C= 1.15 Imp-D= 1.22 Imp-B =1.54

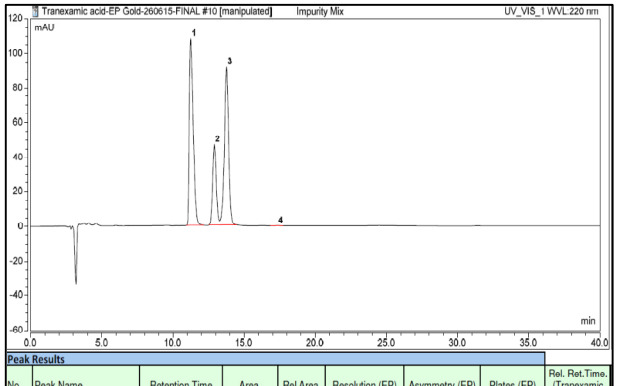
CHROMATOGRAMS:



Peak Results

No.	Peak Name	Retention Time (min)	Area (mAU*min)	Rel.Area (%)	Resolution (EP)	Asymmetry (EP)	Plates (EP)	Rel. Ret.Time. (Tranexamic Acid)
1	Tranexamic Acid	11.492	1.573	2.18	0.00	1.14	12980	1.00
2	Impurity-C	12.982	70.672	97.82	3.48	1.11	13047	1.13

System Suitability:



Peak Results

No.	Peak Name	Retention Time (min)	Area (mAU*min)	Rel.Area (%)	Resolution (EP)	Asymmetry (EP)	Plates (EP)	Rel. Ret.Time. (Tranexamic Acid)
1	Tranexamic Acid	11.247	34.306	43.28	0.00	1.72	7819	1.00
2	Impurity-C	12.918	13.558	17.11	3.48	n.a.	12866	1.15
3	Impurity-D	13.772	31.372	39.58	4.92	0.96	11215	1.22
4	Impurity-B	17.350	0.023	0.03	12.48	1.02	21616	1.54

Impurity Mix: