

Impurities test for Carbamazepine (USP-38 method):

SAMPLE PREPARATION:

Standard Stock solution: 0.02mg/ml of Carbamazepine RS, Impurity A and Impurity-B in Methanol.

Standard solution: 0.001mg/ml of Carbamazepine RS, Impurity A and Impurity-B from stock solution in Diluent.

System suitability stock solution: 0.1mg/ml of Carbamazepine and 0.5mg/ml of Impurity-A in Methanol.

System suitability solution: 0.01mg/ml of Carbamazepine and 0.05mg/ml of Impurity-A from system suitability stock solution in diluent.

CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC

Column: Hypersil Gold CN (4.6*250mm, 5um, p/n: 25805-254630, lot no.: 12258)

Diluent: 50:50 (Methanol: Water)

Mobile phase: Methanol: Tetrahydrofuran: Water (12:3:85) Add 0.22ml of formic acid and 0.5 ml of Triethylamine to it.

Separation Mode: Isocratic

Column temperature: 25°C

Flow rate: 1.5 mL/min

Injection Volume: 20 µl

Detector wavelength: UV230 nm

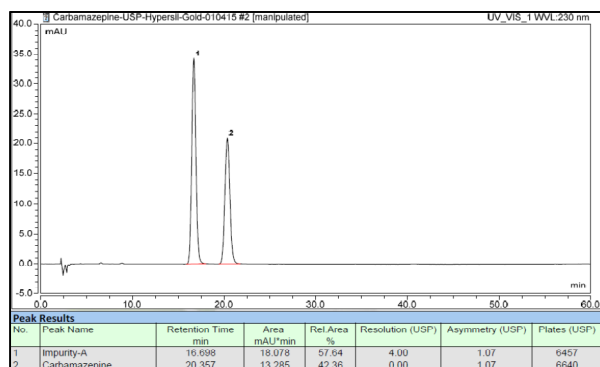
Run Time: 60min

System Suitability Results:

Sr. No.	Parameters	USP Criteria	Obtained Results
1	Resolution between Carbamazepine related compound A and Carbamazepine	NLT 1.70	4.00

CHROMATOGRAMS:

System Suitability:



Impurity Mix:

