

Impurities test for Piracetam (EP-8.0 method):

SAMPLE PREPARATION:

Test Solution (a): Dissolve 50.0 mg of Piracetam to be examined in a mixture of 10 volumes of acetonitrile and 90 volumes of water and dilute to 100.0 ml with same mixture of solvents.

Test Solution (b): Dilute 10.0 ml of test solution (a) in 50 ml with 10 volumes of acetonitrile and 90 volumes of water.

Reference solution (a): Dissolve 5 mg of the Piracetam and 10 μ l of 2-pyridylidine in a mixture of 10 volumes of acetonitrile and 90 volumes of water and dilute to 100.0 ml with same mixture of solvents

Reference solution (b): Dilute 1.0 ml of test solution (a) in 100 ml with 10 volumes of acetonitrile and 90 volumes of water. Dilute 5.0 ml of this solution in 50 ml with 10 volumes of acetonitrile and 90 volumes of water.

Reference solution (c) Dissolve 50.0 mg of Piracetam to be examined in a mixture of 10 volumes of acetonitrile and 90 volumes of water and dilute to 100.0 ml with same mixture of solvents.

CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC

Column: Syncronis C18 (4.6*150mm, 5um, p/n 97105-154630, lot no.:11811)

Mobile phase: Acetonitrile: Buffer (10:90) pH 6.0 with dilute phosphoric acid

Buffer: 1.0 g/L of Dipotassium hydrogen phosphate

Separation Mode: Isocratic

Column temperature: 25°C

Flow rate: 1.0 mL/min

Injection Volume: 20 μ l

Detector wavelength: UV 205nm

Run Time: 25min

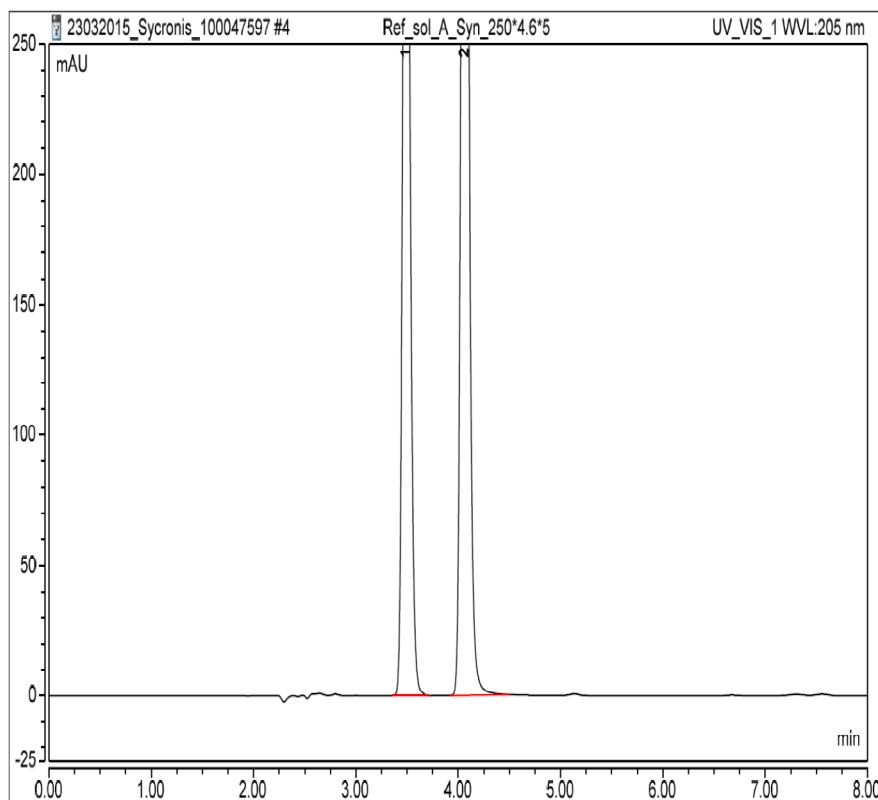
System Suitability Results:

Sr. No.	Parameters	USP Criteria	Obtained Results
1	• Resolution between Piracetam & imp A.	• NLT 3.0	• 4.77
2	• Symmetry factor for Piracetam	• NMT 2.0	• 1.16

CHROMATOGRAMS:

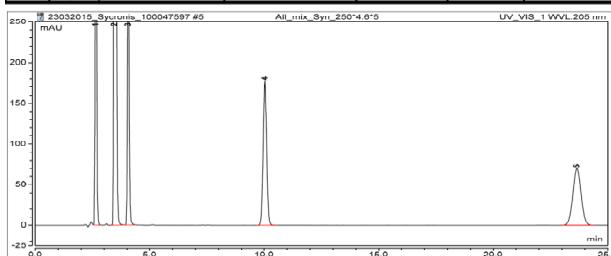
System Suitability:

Impurity Mix:



Peak Results

No.	Peak Name	Retention Time min	Area mAU*min	Rel.Area %	Resolution (EP)	Asymmetry (EP)	Plates (EP)
1	Piracetam	3.490	36.146	41.32	0.00	1.16	13148
2	Impurity A	4.063	51.339	58.68	4.77	1.14	18621



No.	Peak Name	Retention Time min	Area mAU*min	Rel.Area %	Resolution (EP)	Asymmetry (EP)	Plates (EP)
1	Impurity D	2.641	40.879	12.08	0.89	1.27	997.9
2	Piracetam	3.491	20.693	6.13	0.60	1.52	18761
3	Impurity A	4.061	20.696	8.77	4.61	1.14	18766
4	Impurity R	10.028	31.260	0.24	31.71	1.03	20853
5	Impurity G	23.653	28.725	8.49	51.35	1.02	21098