Impurities test for Metronidazole (EP-8.0 method):

SAMPLE PREPARATION:

Test Solution: Dissolve 0.05gm of Metronidazole in Mobile phase and dilute to 100ml with mobile phase

Reference solution (a): Dilute 1ml of test solution to 100ml with mobile phase, dilute 1ml of this solution to 100ml with mobile phase.

Reference solution (b): Dissolve 5mg of Metronidazole impurity A CRS in mobile phase, add 10 ml of test solution, dilute to 100ml with mobile phase, and dilute 1ml to 100 ml with mobile phase.

CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC
Column: Syncronis C18 (4.6*250mm, 5um, p/n 97105-254630, lot no.: 11811)

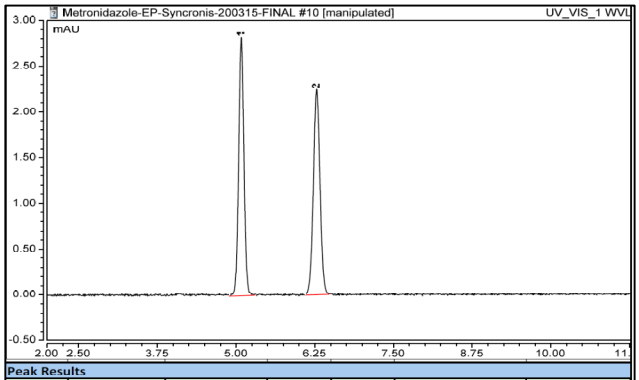
Mobile phase: 30:70 (Methanol: 1.36 g/L solution of potassium Dihydrogen phosphate.
Separation Mode: Isocratic
Column temperature: 25˚C
Flow rate: 1.0 mL/min
Injection Volume: 10 µl
Detector wavelength: UV315 nm
Run Time: 21min

System Suitability Results:

Sr. No.	Parameters	USP Criteria	Obtained Results
1	Resolution b/w Metronidazole and Impurity-A	NLT 2.0	6.9
2	Tailing Factor for Metronidazole peak	NMT 2.0	1.0

CHROMATOGRAMS:

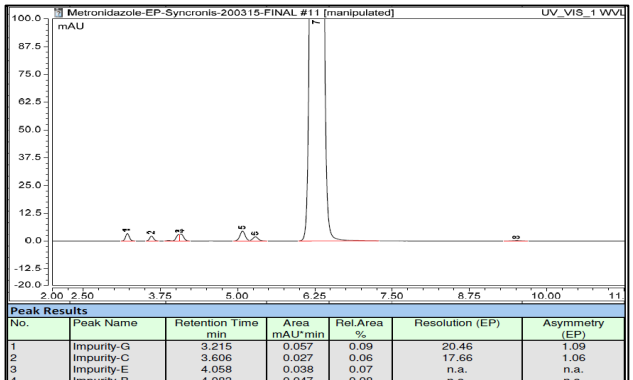
System Suitability:



Peak Results

No.	Peak Name	Retention Time min	Area mAU*min	Rel.Area %	Resolution (EP)	Asymmetry (EP)
1	Impurity-A	5.083	0.075	49.59	6.97	1.02
2	Metronidazole	6.278	0.077	50.41	0.00	1.03

Impurity Mix:



Peak Results

No.	Peak Name	Retention Time min	Area mAU*min	Rel.Area %	Resolution (EP)	Asymmetry (EP)
1	Impurity-G	3.215	0.057	0.09	20.46	1.09
2	Impurity-C	3.606	0.027	0.06	17.66	1.06
3	Impurity-E	4.058	0.038	0.07	n.a.	n.a.
4	Impurity-B	4.083	0.047	0.08	n.a.	n.a.
5	Impurity-A	5.080	0.205	0.17	6.90	n.a.
6	Impurity-D	5.286	0.040	0.08	5.65	n.a.
7	Metronidaole	6.278	66473.363	99.42	0.00	1.02
8	Component-8	9.515	0.001	0.01	13.56	0.95