

Quantitative Analysis of Acetic Acid in Drug Composition on Amaze HA Column

Equipment

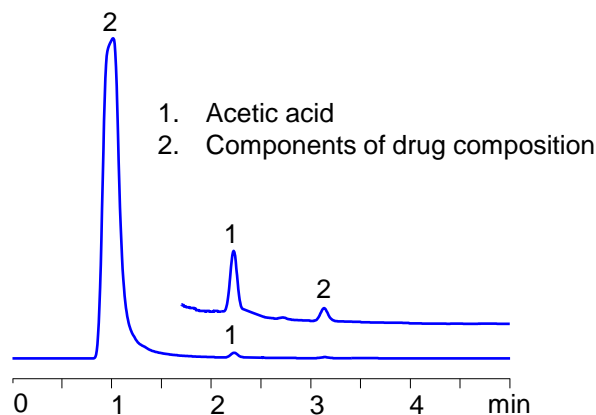
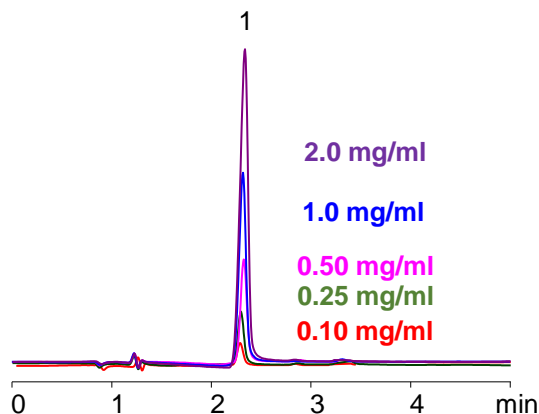
Agilent 1100 HPLC system with DAD
Analytical Balance
HPLC Column: Amaze HA, 4.6x100 mm, 3 um, 100A

Materials:

Acetic acid (Aldrich catalog #AX0074)
Drug composition M1723
ACN (Tedia, catalog #AS1127)
Distilled water (Aldrich, catalog #270733)
Ammonium Phosphate dibasic (Aldrich, catalog #09709)
Phosphoric acid (Aldrich, catalog #345245)

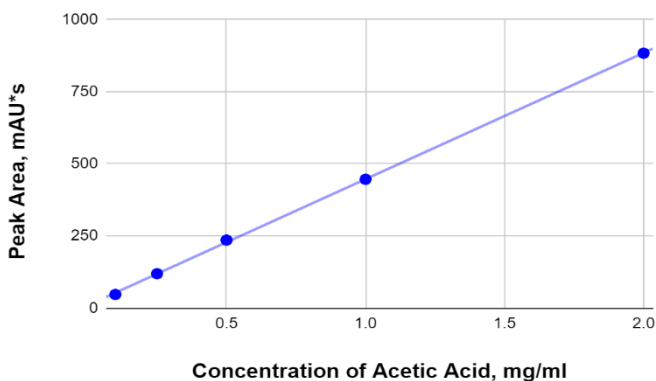
Method Description

HPLC Pump set up: A: DI water, B: Acetonitrile, C: 100 mM Ammonium phosphate dibasic pH 5.6
A: Mobile phase composition: 25% ACN with 5 mM ammonium phosphate pH 5.6 buffer
Mobile phase delivery: A: 70%, B: 25%, C: 5%



Acetic Acid Calibration and Sample Analysis

Calibration Plot for Acetic Acid, mg/ml (RSD 0.999)



Column: Amaze HA
Dimensions: 3.0 x 100 mm, 3 um, 100A
Mobile phase: 25% ACN with 5 mM AmPh pH 5.6
Flow: 0.5 ml/min
Detection: 205 nm
Sample: Standards and drug composition
Injection: 2 uL

Concentration, mg/ml	Peak Area Average, mAU*s	Peak Area, Inj. 1, mAU*s	Peak Area, Inj. 2, mAU*s	Peak Area, Inj. 3, mAU*s	Concentration of Acetic Acid, mg/ml
0.1	47	44	48	49	-
0.25	119	122	117	118	-
0.5	235	240	234	232	-
1	446	454	439	445	-
2	883	883	884	881	-
Drug composition M1723	167	166	169	165	0.36