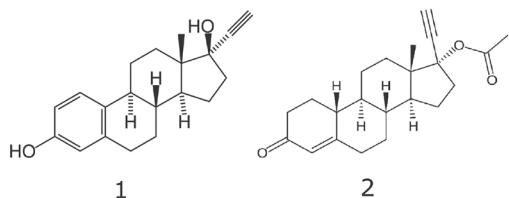
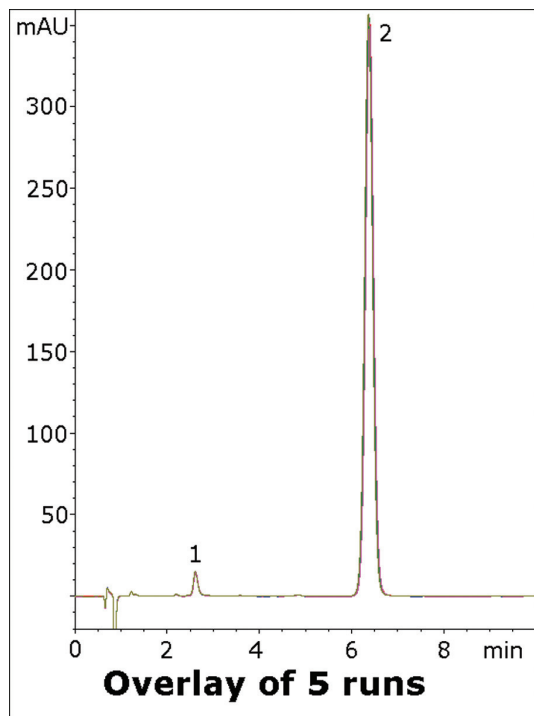


Femhrt® Hormone Replacement Tablet

Separation of ethinylestradiol and norethisterone acetate



Note: Ethinyl estradiol is a synthetic derivative of estradiol. Norethisterone acetate is a prodrug of norethisterone in the body.

Method Conditions

Column: Cogent Bidentate C8™, 4µm, 100Å

Catalog No.: 40008-75P

Dimensions: 4.6 x 75 mm

Mobile Phase: 50% DI H₂O / 50% acetonitrile / 0.1% formic acid

Injection vol.: 20µL

Flow rate: 1.0 mL/min

Detection: UV 240 nm

Sample: A femhrt® tablet containing 0.5 mg norethisterone acetate and 2.5µg ethinylestradiol was ground and added to a 5 mL volumetric flask. A portion of 50/50 DI H₂O / acetonitrile mixture was added and the flask was sonicated for 10 minutes. Then it was diluted to mark and filtered with a 0.45µm nylon syringe filter (MicroSolv Tech Corp.). The filtrate was used for injections. Peak identities were confirmed by individual standards.

Peaks: 1. Ethinylestradiol
2. Norethisterone acetate

t₀: 0.9 min

Discussion

In this simple isocratic HPLC method, two hormones from a tablet extract are separated using the Bidentate C8™ column. Both analytes are adequately retained while keeping the run time to 10 minutes. The USP method for assay of the two compounds is lengthy and unnecessarily complex, while this chromatographic method is rapid and easy to automate. In addition, the precision of the method is demonstrated through the overlay of five runs shown in the figure.