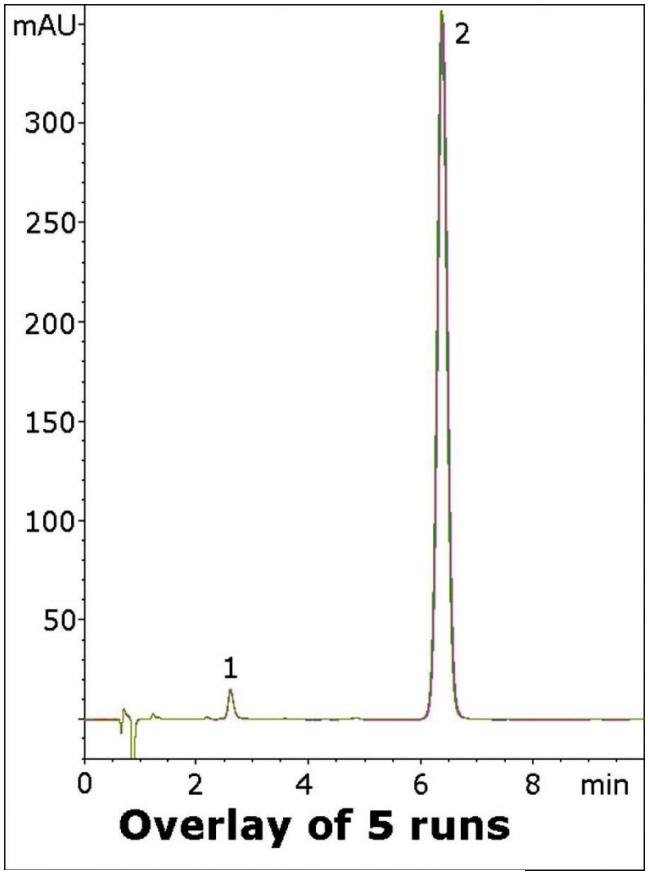
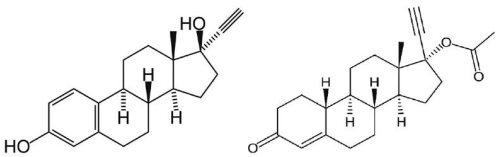
Hormone Replacement Tablet Analyzed with HPLC – AppNote

Isocratic Separation of Ethinylestradiol and Norethisterone Acetate

In this simple HPLC Method, two hormones from a tablet extract are separated. Both analytes are adequately retained while keeping the run time to 10 minutes.

The USP Monograph Method for Assay of the two compounds is lengthy and complex, while this Method is rapid and easy to automate. In addition, the Precision of the Method is demonstrated through the overlay of five overlaid Chromatograms shown in the Figure below.





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Peaks:

1. Ethinylestradiol
2. Norethisterone acetate

Method Conditions

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

Catalog No.: 40008-75P
Dimensions: 4.6 x 75mm
Mobile Phase: 50:50 DI Water / Acetonitrile with 0.1% Formic Acid
Injection vol.: 20µL
Flow rate: 1.0mL / minute
Detection: UV @ 240nm
Sample Preparation: A Femhrt® tablet containing 0.5mg Norethisterone Acetate and 2.5µg Ethinylestradiol was ground and added to a 5mL volumetric flask. A portion of 50:50 DI Water / 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.
t_0: 0.9 minutes

***Note**: Ethinylestradiol is a synthetic derivative of Estradiol. Norethisterone Acetate is a precursor of Norethisterone in the body.*

Attachment

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