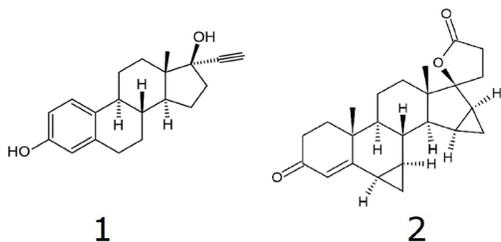
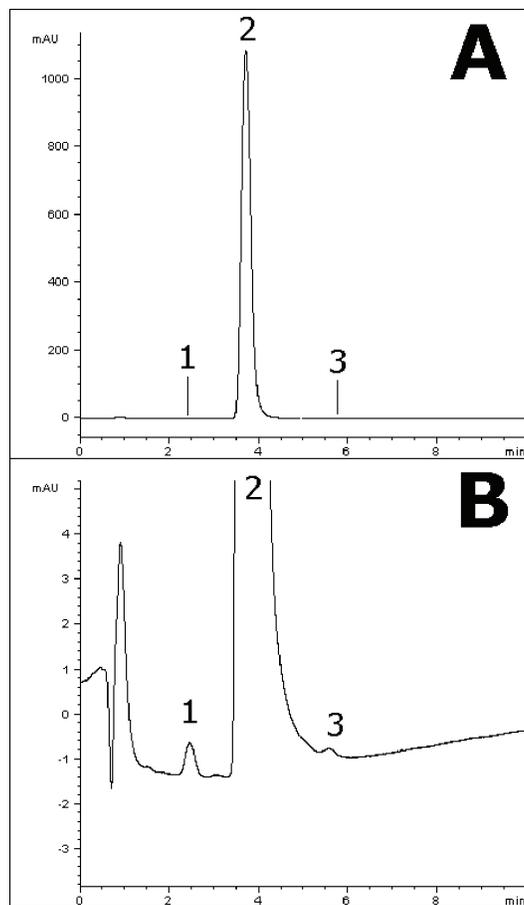


Ocella® Tablet

Separation of drospirenone and ethinyl estradiol



Note: The combination formulation of drospirenone and ethinyl estradiol is used as a contraceptive and also to alleviate symptoms of premenstrual dysphoric disorder.

Method Conditions

Column: Cogent Bidentate C18 2.0™, 2.2µm, 120Å

Catalog No.: 40218-05P-2

Dimensions: 2.1 x 50 mm

Mobile Phase: 50% DI water / 50% Acetonitrile (v/v)

Injection vol.: 4.0 microL

Flow rate: 0.2mL/min

Detection: UV 265 nm

Peaks: 1. Ethinyl estradiol
2. Drospirenone
3. Impurity

Sample: Ocella® tablet (3 mg strength drospirenone and 0.03 mg strength ethinyl estradiol) was ground and added to a 10 mL volumetric flask containing a portion of acetonitrile. It was sonicated for 10 min and diluted to mark. After mixing, a portion was filtered (0.45 µm, nylon) and used for HPLC injections.

Discussion

Separation of two hormone analytes is achieved in this application. The Cogent Bidentate C18 2.0 column was useful in obtaining not only good chromatographic selectivity but also high-efficiency peaks. This can be helpful since ethinyl estradiol is present at a much lower concentration than drospirenone and therefore can be difficult to detect; the high efficiency can contribute to a stronger signal in detection. Furthermore, the isocratic mobile phase is very simple to prepare or even obtain premixed, allowing for streamlined routine assays of this formulation in QC laboratories.

Figure A depicts the full view of the chromatogram, with the drospirenone peak shown in its entirety. Figure B shows a zoom in view so that the tiny ethinyl estradiol peak can be seen more clearly. There is even an impurity peak observed eluting after drospirenone.