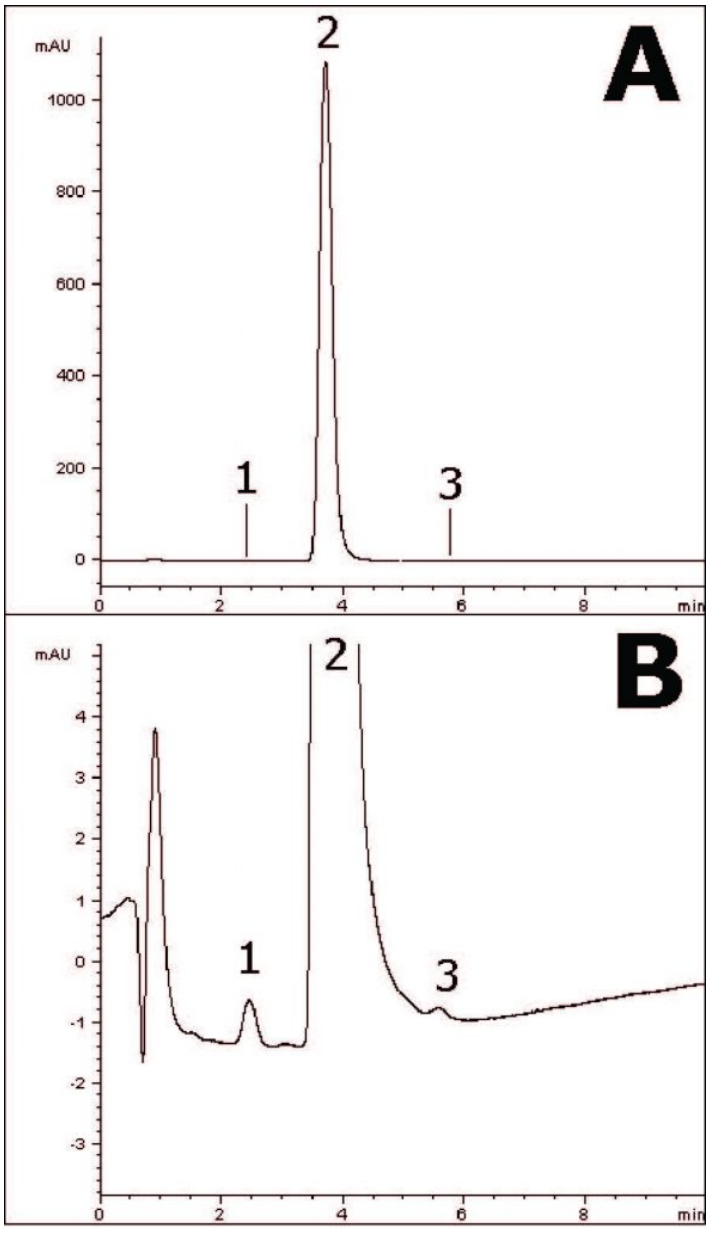
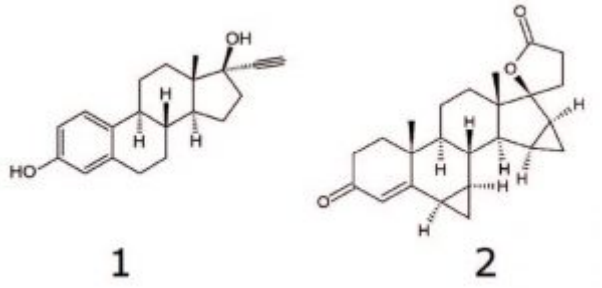
Ocella® Tablet Analyzed with HPLC – AppNote

Separation of Drospirenone and Ethinyl Estradiol

Good Selectivity with high Efficiency Peaks can be achieved analyzing Ocella Tablets. 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 thus increasing Sensitivity. Furthermore, the isocratic Mobile Phase is very simple to prepare or even obtain pre-mixed, allowing for streamlined routine Assays of this formulation in QC laboratories.

Figure A shows 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 and measured. There is even an Impurity Peak observed eluting after Drospirenone.





Peaks:

1. Ethinyl estradiol
2. Drospirenone
3. Impurity

Method Conditions

Column: Cogent Bidentate C18 2.o™, 2.2µm, 120Å

Catalog No.: 40218-05P-2

Dimensions: 2.1 x 50mm

Mobile Phase: 50:50 DI Water / Acetonitrile (v/v)

Injection vol.: 4.0µL

Flow rate: 0.2mL / minute

Detection: UV @ 265nm

Sample Preparation: Ocella® Tablet *(3mg strength Drospirenone and 0.03mg strength Ethinyl Estradiol)* was ground and added to a 10mL volumetric flask containing a portion of Acetonitrile. It was sonicated for 10 minutes and diluted to mark. After mixing, a portion was filtered (0.45µm, Nylon Syringe Filter) and used for HPLC injections.

Note: *The combination formulation of Drospirenone and Ethinyl Estradiol is used as a contraceptive and also to alleviate symptoms of premenstrual dysphoric disorder.*

Attachment

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