

## Lab Highlights

LAH 0067 10/82  
Doc # M1001  
AN/PA,/PC,/HR/CTQUANTITATIVE ASSAY OF A STEROID SOLUTION ON ULTRASTYRAGEL™ COLUMNS

A single 100Å ULTRASTYRAGEL™ column provided baseline resolution of Halcinonide (a synthetic corticosteroid) and BHT (an antioxidant) from a topical preparation. Selective UV detection at 254 nm provided the signal for quantitation. Inspection of the chromatogram from the R401 indicates that the polyethylene glycol 300 carrier is only partially resolved from the active components. As the data in Table I shows, the assay is very reproducible, and the quantity of Halcinonide found (0.93 to 1.03 g/g of solution) is close to the label concentration of 1.00 g/g.

TABLE IASSAY OF HALCINONIDE SOLUTIONS \*

<u>Lot</u>	<u>Halcinonide</u> <u>(mg/g)</u>	<u>BHT</u> <u>(mg/g)</u>
A	9.937 ± 0.0079 (± 0.85%)	0.418 ± 0.016 (± 3.7%)
B	1.025 ± 0.0031 (± 0.30%)	0.421 ± 0.011 (± 2.4%)
C	0.929 ± 0.0029 (± 0.31%)	0.402 ± 0.0006 (± 0.14%)

The major advantages of GPC for this assay are:

- NO "METHODS DEVELOPMENT"
- SIMPLE, EASY SAMPLE PREPARATION: DISSOLUTION

The assay was run by dissolving 1 g of sample in 100 ml of THF, filtering and injecting. No development of the separation was required. When the first sample eluted from the column (before the total volume of the column), the separation development was complete. Two additional injections of known standards confirmed peak identity and, except for calibration, the method was complete.

\* Quantitation done on Data Module in LC mode

See reverse side for chromatogram.

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