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Note

Gas chromatographic determination of Stanozolol in veterinary suspensions

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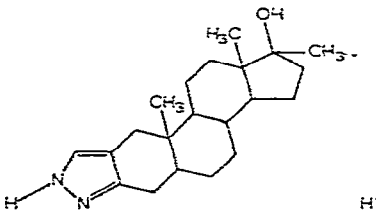
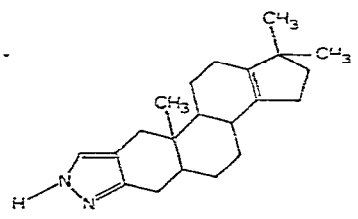
The need for a stability-indicating assay procedure for Stanozolol in veterinary suspensions led to the development of a gas chromatographic procedure for not only the intact drug (17α-methyl-17β-hydroxy-5α-androstane-3,2c-pyrazole; I) but also its major degradation product, the 17-dehydro analog (18-nor-17,17-dimethylandrost-13-eno-3,2c-pyrazole; II).



I



II

The preparation of interest was Winstrol-V Suspension (Winthrop Laboratories, Div. Sterling Drug, Inc.), of the following composition:

	mg/ml
Stanozolol N.F.[1]	50.00
Thimerosol N.F.	0.50
Polysorbate 80 U.S.P.[2]	1.00
Sodium chloride U.S.P.	9.00

The method presented works very well for a quality control procedure, since it is rapid, precise, and requires no prior separation of the drug from the other constituents of the suspension. It also shows promise as a stability-indicating method as indicated by the excellent separation of the intact drug from its 17-dehydro analog.

EXPERIMENTAL AND RESULTS

Suspensions taken for analysis were prepared according to the commercial formulation by Winthrop Laboratories, Div. Sterling Drug. The suspension was

shaken on a mechanical shaker for 10–15 min, and a portion equivalent to about 50 mg (1 ml) was quickly and completely transferred to a 10-ml volumetric flask. To this was added 1.0 ml of a 50 mg/ml methyl androstanalone internal standard solution in dimethylformamide (DMF) (analytical-reagent grade, Mallinckrodt, St. Louis, Mo., U.S.A.) and then diluted to volume with DMF. This resulted in a clear solution. A reference standard was similarly prepared, using 50.0 mg of Stanozolol N.F. Reference Standard in place of the 1.0 ml of suspension, and adding 1 mg of the 17-dehydro compound. 2-μl portions were injected into a Perkin-Elmer Model 900 gas chromatograph containing a glass column 6 ft. × 4 mm I.D. packed with 80–100 mesh Chromosorb W AW DMCS coated with 10% SE-30. The oven temperature was set at 300° and the injection port temperature at 350°. A flame ionization detector was used, with the manifold at 350°. Helium was used as the carrier gas, at a flow-rate of 60 ml/min. The hydrogen and air flow-rates were approximately 30 and 300 ml/min, set to maximize detector response. Under these conditions, the retention times were 1.52 min for methyl androstanalone, 2.17 min for the 17-dehydro compound and 3.42 min for Stanozolol (Fig. 1).

Triplicate determinations were made, yielding an average assay value for Sta-

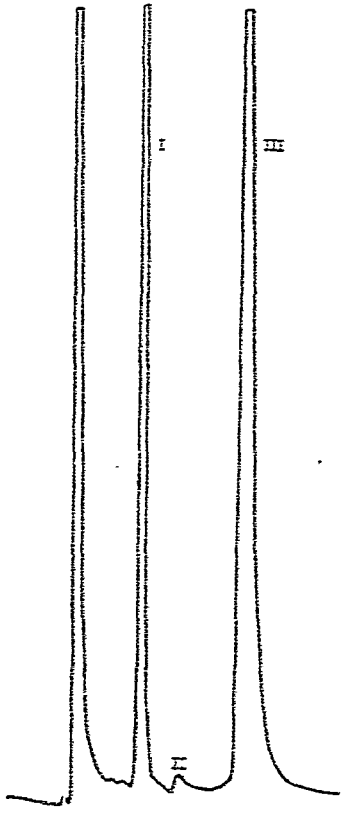


Fig. 1. Gas–liquid chromatogram of Stanozolol. I = Methyl androstanalone; II = 17-dehydro compound; III = Stanozolol.

nozolol of 49.51 mg/ml (range 49.04–49.76 mg/ml), with a relative standard deviation of 0.33%. Calculations were handled by a Perkin-Elmer PEP-1 processor, in the internal standard mode.

ACKNOWLEDGEMENT

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REFERENCES

1 *National Formulary*, American Pharmaceutical Association, Washington, D.C., 14th ed., 1975.
2 *The United States Pharmacopeia*, United States Pharmacopeial Convention, Rockville, Md., 19th ed., 1975.