REPORT ON ETHINYL ESTRADIOL

Scope of the Survey

This study covered Ethinyl Estradiol Tablets U.S.P. XVIII, marketed as a single active ingredient product in tablet form, in the following dosages: 0.02 mg., 0.05 mg., and 0.5 mg.

Of the seven domestic formulators known to produce Ethinyl Estradiol Tablets, samples of batches from four firms were collected in this survey. Batches varied in size from slightly under 200,000 tablets to slightly more than 2,000,000 tablets. Eight batches from four different firms were tested. The output of three firms (Ferndale Laboratories, Inc.; Organon Inc.; and Marshall Pharmacal) was unavailable for sampling.

Sampling Information

Samples were collected under FDA's FORDS (Formulator-Oriented Rx Drug Studies) Program from the formulators (manufacturing plant or primary distribution warehouse) or from their branch warehouses or major accounts. No collections were made at locations more than once removed from the manufacturer. Samples were collected from batches released for distribution by the firms' quality control.

Laboratory Tests

Samples were analyzed by semi-automated procedure as described under Method No. 24 of the FDA Drug Autoanalysis Manual. Testing was performed on each of six sub-samples from each batch. Where outside of compendial limits, results were verified by the U.S.P. Method.

Summary of Results

Of the eight samples analyzed (see Table 1) one sample of 0.05 mg. tablets was found defective due to lack of content uniformity, with a sample defect rate for the survey of 12.5 percent. No samples of other dosage strengths were defective.