

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 10195

DEFENSE MEDICAL PURCHASE DESCRIPTION		NUMBER 2	DATE 29 April 1971
FEDERAL STOCK NO. 6505-935-5P36	ITEM IDENTIFICATION ETHYNODIOL DIACETATE WITH MESTRANOL TABLETS, 63s		UNIT Box

1. SCOPE

1.1 This specification covers Ethynodiol Diacetate with Mestranol Tablets, 63s.

2. APPLICABLE DOCUMENTS

2.1 Unless otherwise indicated, the issue in effect on date of invitation for bids or request for proposals of the specifications and standards referenced in the body of this specification shall apply to the extent specified herein. These documents may be obtained as directed by the contracting officer.

3. REQUIREMENTS

3.1 Material. Shall be Ethynodiol Diacetate with Mestranol Tablets and shall be in accordance with all applicable requirements of Fed. Std. No. 140a, dated 30 October 1966, and Amendment-1, dated 25 March 1970, and as specified herein:

S2. Classification. Shall be type I, class 1.

Shall be suitable for use as an oral contraceptive.

SF.3 The following additional requirements and tests are added to this paragraph:

Each tablet shall contain the following:

Ethynodiol Diacetate - - - - - 1.0 mg
Mestranol - - - - - 0.1 mg

The tablets shall assay to contain between 93.0 percent and 107.0 percent of the labeled strength of Ethynodiol Diacetate, and between 90.0 percent and 115.0 percent of their labeled strength of Mestranol, when assayed as specified in 4.3.1.

The Ethynodiol Diacetate powder used in the manufacture of the tablets shall be in accordance with the tests, standards, and requirements of the U.S.P., including any supplements or revisions thereto.

The Mestranol powder used in the manufacture of the tablets shall be in accordance with the tests, standards, and requirements of the U.S.P. and, in addition, shall comply with the following:

Methoxyl (radical). Shall contain not less than 9.75 percent and not more than 10.25 percent of methoxyl (radical) when assayed by an appropriate, reproducible method.

SSC-1

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