

Contains Nonbinding Recommendations
Draft – Not for Implementation
Draft Guidance on Mestranol; Norethindrone
October 2024

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Active Ingredients:	Mestranol; Norethindrone
Dosage Form:	Tablet
Route:	Oral-28
Strength:	0.05 mg; 1 mg
Recommended Study:	One in vivo bioequivalence study with pharmacokinetic endpoints
1.	Type of study: Fasting Design: Single-dose, two-treatment, two-period crossover in vivo Strength: 0.05 mg; 1 mg Subjects: Healthy non-pregnant, non-lactating females Additional comments: None
Analytes to measure:	Ethinyl estradiol (active metabolite of mestranol) and norethindrone in plasma
Bioequivalence based on (90% CI):	Ethinyl estradiol (active metabolite of mestranol) and norethindrone
Waiver request of in vivo testing:	Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution>. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.