

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 21-241/S-003

CHEMISTRY REVIEW

**CHEMIST REVIEW
OF SUPPLEMENT**

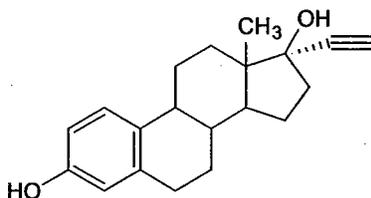
1. **ORGANIZATION:** DRUDP, HFD-580
2. **NDA NUMBER:** 21-241/SCM 003
3. **SUPPLEMENT NUMBERS/DATES:**
Letterdate: 22-Nov-2002
Stampdate: 22-Nov-2002
4. **AMENDMENTS/REPORTS/DATES:**
Letterdate:
Stampdate:
5. **RECEIVED BY CHEMIST:** 27-Nov-2002

6. **APPLICANT NAME AND ADDRESS:** Ortho-McNeil Pharmaceuticals, Inc.
1000 Route 202 South
P.O. Box 300
Raritan, NJ 08869-0602
(908)-704-9757

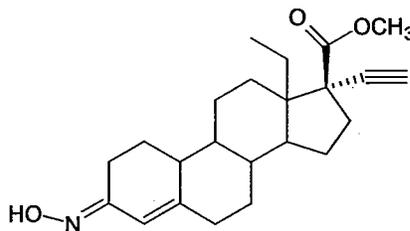
7. **NAME OF DRUG:** Ortho Tri-Cyclen Lo

8. **NONPROPRIETARY NAME:** Norgestimate/Ethinyl estradiol

9. **CHEMICAL NAME/STRUCTURE:**



Ethinyl estradiol (EE)



Norgestimate (NGM)

Ethinyl estradiol (EE): 19-Nor-17 α -pregn-1,3,5(10)-trien-20-yne-3, 17-diol

Norgestimate (NGM): (+)-13-Ethyl-17-hydroxy-18,19-dinor-17 α -pregn-4-en-20-yne-3-one oxime acetate

10. **DOSAGE FORM(S):** Oral tablets

11. **POTENCY:** 180 mcg/25 mcg (NGM/EE); 215 mcg/25 mcg (NGM/EE); 250 mcg/25 mcg (NGM/EE)

12. **PHARMACOLOGICAL CATEGORY:** Estrogen/Progestin, Oral contraceptive

13. **HOW DISPENSED:** Rx

14. **RECORDS & REPORTS CURRENT:** Yes

15. **RELATED IND/NDA/DMF:** DMF _____

16. SUPPLEMENT PROVIDES FOR: An alternate manufacturing site for one of the drug substances (ethinyl estradiol).

17. SPECIAL PRODUCTS: YES NO

(If yes, fill out the form for special products and deliver to TIA through team leader for data entry)

18. COMMENTS:

The current supplement provides for an alternate manufacturing site for the ethinyl estradiol drug substance. The address is listed below:

Ethinyl estradiol is manufactured under DMF—— This DMF was reviewed as adequate on 01-May-2002 (please refer to the review by A. Raw, Ph.D., HFD-623). The manufacturing process at the above alternate site does not differ from that of the current site. The Sponsor has committed to stability testing of the first commercial batch of each strength of drug product manufactured at the new site, in accordance with the currently approved stability protocol for NDA 21-241. Results from this stability testing will be included in the Annual Reports for this product.

The Sponsor has fulfilled the criteria for submission of this information as a CBE-30 supplement under Section VI of the "Changes to an Approved NDA or ANDA" Guidance. A request was submitted to EES on November 29, 2002 and returned as acceptable on December 2, 2002 (see attached report from EES).

19. CONCLUSIONS AND RECOMMENDATIONS:

This CBE-30 supplement may be **approved**. Issue an Approval Letter.

20. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Sarah C. Pope, Ph.D.		04-Dec-2002

cc: Original: NDA 21-241/SCM-003
HFD-580/Division File
HFD-580/D. Spell-Lesane
HFD-580/D.T. Lin/S. Pope

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Sarah Pope
12/10/02 10:02:56 AM
CHEMIST

David T. Lin
12/10/02 10:30:23 AM
CHEMIST
I concur.