

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-633

Chemistry Review(s)

NDA 21-633

**FEMTRACE®
Estradiol Acetate Tablets**

Warner Chilcott Company, Inc.

**Sarah C. Pope, Ph.D.
Division of Reproductive and Urologic Drug Products
(DRUDP, HFD-580)**

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Chemistry Review Data Sheet

1. NDA 21-633
2. REVIEW #2
3. REVIEW DATE: 18-AUG-2004
4. REVIEWER: Sarah C. Pope, Ph.D.
5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
Chemistry Review #1	06-JUL-2004

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Amendment	16-AUG-2004

7. NAME & ADDRESS OF APPLICANT:

Name: Warner Chilcott Company, Inc.
Rockaway 80 Corporate Center
Address: 100 Entrprise Drive, Suite 280
Rockaway, NJ 07866
Representative: Alvin Howard
Telephone: (973)-442-3200

8. DRUG PRODUCT NAME/CODE/TYPE:

a) Proprietary Name: FEMTRACE®
b) Non-Proprietary Name (USAN): Estradiol acetate tablets
c) Code Name/# (ONDC only): E3A

CHEMISTRY REVIEW

Chemistry Review Data Sheet

d) Chem. Type/Submission Priority (ONDC only):

- Chem. Type: 3
- Submission Priority: Standard

9. LEGAL BASIS FOR SUBMISSION: N/A

10. PHARMACOL. CATEGORY: estrogen, treatment of severe vasomotor symptoms.

11. DOSAGE FORM: Tablet

12. STRENGTH/POTENCY: 0.45 mg, 0.9 mg, and 1.8 mg

13. ROUTE OF ADMINISTRATION: Oral

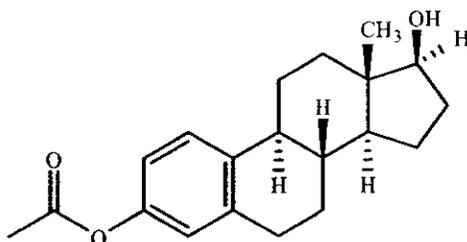
14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:



Estradiol 3-acetate (E3A)
Estra-1,3,5(10)-triene-3,17 β -diol-3-acetate
C₂₀H₂₆O₃
MW = 314.42 g/mole

CHEMISTRY REVIEW

Chemistry Review Data Sheet

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
	II		Estradiol acetate	1	Adequate	17-MAY-2004	Reviewed by Dr. S. Pope
	III			1	Adequate	20-APR-2004	Reviewed by Dr. S. Pope
	III			1	Adequate	20-APR-2004	Reviewed by Dr. S. Pope
	III			3	Adequate	03-APR-2001	Reviewed by Dr. P. Maturu
	III			3	Adequate	22-APR-2002	Reviewed by Dr. R. Frankewich
	III			1	Adequate	15-SEP-2000	Reviewed by Dr. R. Seevers
	III			1	Adequate	12-JUL-2004	Reviewed by Dr. L. Hsieh
	III			1	Adequate	28-FEB-2003	Reviewed by Dr. M. Heiman
	III			1	Adequate	09-APR-2004	Reviewed by Dr. R. Frankewich

¹ Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 – Type 1 DMF

3 – Reviewed previously and no revision since last review

4 – Sufficient information in application

5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

CHEMISTRY REVIEW

Chemistry Review Data Sheet

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A	N/A	N/A
EES	Acceptable	12-NOV-2003	Ms. J. D'Ambrogio
Biopharm	Acceptable	30-JUL-2004	Dr. S. Ortiz
LNC	N/A	N/A	N/A
Methods Validation	Methods will be submitted post-approval.	07-JUL-2004	Dr. S. Pope
ODS	Trade name unacceptable - resolved by Division.	15-APR-2004	Kim Culley
EA	Categorical exclusion claimed.	07-JUL-2004	Dr. S. Pope
Microbiology	N/A	N/A	Solid oral dosage form.

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The Chemistry Review for NDA 21-633

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

From a Chemistry, Manufacturing, and Controls point of view, this NDA may be Approved.

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

None

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug Product

FEMTRACE is a solid oral tablet, containing estradiol-3-acetate (E3A). FEMTRACE will be marketed in three dosage strengths: 0.45 mg, 0.9 mg, and 1.8 mg. All strengths will be marketed for the treatment of moderate to severe vasomotor symptoms associated with menopause.

FEMTRACE tablets (0.45 mg) are cream, round, biconvex tablets debossed with "WC 389" on one side and product logo on the other. FEMTRACE tablets (0.9 mg and 1.8 mg) are identical in visual assessment to the 0.45 mg dosage strength, with the exception of color. FEMTRACE tablets (0.9 mg) and (1.8 mg) are white and yellow in color, respectively.

FEMTRACE tablets are manufactured [] followed by [] Inactive excipients used in the manufacture of FEMTRACE tablets include: ferric oxide (0.45 mg and 1.8 mg only), povidone, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, [] silicon dioxide, magnesium stearate, and [] acetic acid.

The drug product will be manufactured and packaged by Pharmaceutics International, Inc. (Hunt Valley, MD). An overall acceptable recommendation for all sites was issued by the Office of Compliance on 12-NOV-2003 (see the attached EER report).

Acceptable specifications have been provided to ensure product quality at release. Specifications include assay and dissolution for the active ingredient, []

1

Once released, the tablets will be packaged in one of two configurations: 1) white []
 [] or 2) white []
 [] 30 mL (7 count) bottles with [] [] The relevant

Executive Summary Section

DMFs for the two proposed packaging configurations have been reviewed and are adequate for this drug product.

[] of realtime stability data has been provided for the three primary stability batches. Additional long term, intermediate, and accelerated stability data has been provided for three pilot scale batches of each dosage strength. According to the data presented in this NDA, a 24-month expiration dating period has been granted for storage at 25°C/60% RH.

Drug Substance

E3A is manufactured under DMF [] All CMC information for the E3A drug substance has been reviewed as part of DMF [] This DMF is currently adequate in support of this NDA (see Chemistry Review #2 by Dr. S. Pope).

B. Description of How the Drug Product is Intended to be Used

FEMTRACE (0.45 mg, 0.9 mg, or 1.8 mg) is administered once daily, for the treatment of severe vasomotor symptoms.

FEMTRACE tablets should be stored at 25°C (77°F), with excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]. When stored under the specified conditions, FEMTRACE tablets have an expiration dating period of two (2) years.

C. Basis for Approvability or Not-Approval Recommendation

Adequate data have been submitted to assure the drug product's identity, strength, quality, purity, potency and stability. Previous labeling issues have been resolved (see Chemistry Review #1). Therefore, from a CMC standpoint, this New Drug Application may be Approved.

III. Administrative**A. Reviewer's Signature****B. Endorsement Block**

S. Pope/18-AUG-2004
M. Rhee/18-AUG-2004
J. Kim/18-AUG-2004

C. CC Block

4 Page(s) Withheld



 § 552(b)(4) Trade Secret / Confidential

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

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this page is the manifestation of the electronic signature.**

/s/

Sarah Pope
8/18/04 04:18:41 PM
CHEMIST

Moo-Jhong Rhee
8/18/04 04:43:14 PM
CHEMIST
I concur

NDA 21-633

**FEMTRACE®
Estradiol Acetate Tablets**

Warner Chilcott Company, Inc.

**Sarah C. Pope, Ph.D.
Division of Reproductive and Urologic Drug Products
(DRUDP, HFD-580)**

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b. Characterization / Proof Of Structure	11
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3. Synthesis / Method Of Manufacture	12
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Chemistry Review Data Sheet

1. NDA 21-633
2. REVIEW #1
3. REVIEW DATE: 06-JUL-2004
4. REVIEWER: Sarah C. Pope, Ph.D.
5. PREVIOUS DOCUMENTS:

Previous Documents

Document Date

None

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Document Date

Original	14-OCT-2003
Amendment	18-DEC-2003
Amendment	17-MAR-2004
Amendment	02-DEC-2003
Amendment	08-APR-2004
Amendment	29-APR-2004
Amendment	27-MAY-2004
Amendment	03-JUN-2004
Amendment	21-JUN-2004
Amendment	01-JUL-2004
Amendment	09-JUL-2004
Amendment	20-JUL-2004
Amendment	04-AUG-2004

7. NAME & ADDRESS OF APPLICANT:

Name: Warner Chilcott Company, Inc.

CHEMISTRY REVIEW

Chemistry Review Data Sheet

Address: Rockaway 80 Corporate Center
100 Entprise Drive, Suite 280
Rockaway, NJ 07866

Representative: Alvin Howard

Telephone: (973)-442-3200

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: FEMTRACE®
- b) Non-Proprietary Name (USAN): Estradiol acetate tablets
- c) Code Name/# (ONDC only): E3A
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 3
 - Submission Priority: Standard

9. LEGAL BASIS FOR SUBMISSION: N/A

10. PHARMACOL. CATEGORY: estrogen, treatment of severe vasomotor symptoms and moderate to severe symptoms of vulvar and vaginal atrophy.

11. DOSAGE FORM: Tablet

12. STRENGTH/POTENCY: 0.45 mg, 0.9 mg, and 1.8 mg

13. ROUTE OF ADMINISTRATION: Oral

14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

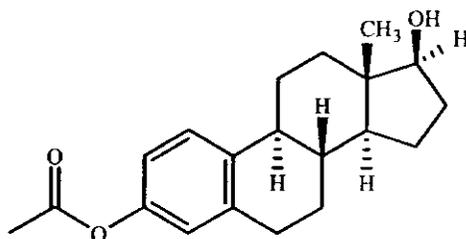
SPOTS product – Form Completed

Not a SPOTS product

CHEMISTRY REVIEW

Chemistry Review Data Sheet

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:



Estradiol 3-acetate (E3A)
 Estra-1,3,5(10)-triene-3,17 β -diol-3-acetate
 $C_{20}H_{26}O_3$
 MW = 314.42 g/mole

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
1	II	1	Estradiol acetate	1	Adequate	17-MAY-2004	Reviewed by Dr. S. Pope
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	III			3	Adequate	03-APR-2001	Reviewed by Dr. P. Maturu
	III			3	Adequate	22-APR-2002	Reviewed by Dr. R. Frankewich
	III			1	Adequate	15-SEP-2000	Reviewed by Dr. R. SeEVERS
	III			1	Adequate	12-JUL-2004	Reviewed by Dr. L. Hsieh
	III			1	Adequate	28-FEB-2003	Reviewed by Dr. M. Heiman
2	III	1		1	Adequate	09-APR-2004	Reviewed by Dr. R. Frankewich

CHEMISTRY REVIEW

Chemistry Review Data Sheet

¹ Action codes for DMF Table:

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Other codes indicate why the DMF was not reviewed, as follows:

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5 - Authority to reference not granted

6 - DMF not available

7 - Other (explain under "Comments")

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION

18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
Biometrics	N/A	N/A	N/A
EES	Acceptable	12-NOV-2003	Ms. J. D'Ambrogio
Biopharm	Acceptable	30-JUL-2004	Dr. S. Ortiz
LNC	N/A	N/A	N/A
Methods Validation	Methods will be submitted post-approval.	07-JUL-2004	Dr. S. Pope
ODS	Trade name unacceptable - resolved by Division.	15-APR-2004	Kim Culley
EA	Categorical exclusion claimed.	07-JUL-2004	Dr. S. Pope
Microbiology	N/A	N/A	Solid oral dosage form.

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On Original*

The Chemistry Review for NDA 21-633

The Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

From a Chemistry, Manufacturing, and Controls point of view, this NDA may be Approved pending resolution of the Package Insert labeling issue (Description section).

B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable

None

II. Summary of Chemistry Assessments

A. Description of the Drug Product(s) and Drug Substance(s)

Drug Product

FEMTRACE is a solid oral tablet, containing estradiol-3-acetate (E3A). FEMTRACE will be marketed in three dosage strengths: 0.45 mg, 0.9 mg, and 1.8 mg. All strengths will be marketed for the treatment of moderate to severe vasomotor symptoms associated with menopause and treatment of moderate to severe symptoms of vulvar and vaginal atrophy associated with menopause.

FEMTRACE tablets (0.45 mg) are cream, round, biconvex tablets debossed with "WC 389" on one side and product logo on the other. FEMTRACE tablets (0.9 mg and 1.8 mg) are identical in visual assessment to the 0.45 mg dosage strength, with the exception of color. FEMTRACE tablets (0.9 mg) and (1.8 mg) are white and yellow in color, respectively.

FEMTRACE tablets are manufactured [redacted], followed by [redacted] Inactive excipients used in the manufacture of FEMTRACE tablets include: ferric oxide (0.45 mg and 1.8 mg only), povidone, lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, [redacted] silicon dioxide, magnesium stearate, and [redacted] acetic acid.

The drug product will be manufactured and packaged by Pharmaceutics International, Inc. (Hunt Valley, MD). An overall acceptable recommendation for all sites was issued by the Office of Compliance on 12-NOV-2003 (see the attached EER report).

Acceptable specifications have been provided to ensure product quality at release. Specifications include assay and dissolution for the active ingredient. [redacted]

51 Page(s) Withheld



§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

**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
8/11/04 03:52:04 PM
CHEMIST

Moo-Jhong Rhee
8/11/04 04:00:57 PM
CHEMIST
I concur

NDA 21-633
Femtrace
(estradiol acetate)

Environmental Assessment

This section is satisfactory (see Chemistry Review page 44).

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NDA 21-633
Femtrace
(estradiol acetate)

Microbiology (validation of sterilization & product sterility) Review

Not Applicable. This is a solid oral dosage form.

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 § 552(b)(4) Trade Secret / Confidential

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

NDA 21-633
Femtrace
(estradiol acetate)

Methods Validation

This section is satisfactory (see Chemistry Review, pages 44-50.)

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ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application:	NDA 21633/000	Action Goal:	
Stamp:	14-OCT-2003	District Goal:	21-JUN-2004
Regulatory Due:	20-AUG-2004	Brand Name:	
FEMTRACE (ESTRADIOL		Estab. Name:	
Applicant: WARNER CHILCOTT		Generic Name:	ESTRADIOL
ACETATE) 0.45/0.9/1.8M		Dosage Form:	TABLETS
100 ENTERPRISE DR STE 280		Strength:	0.45, 0.9, 1.8
ACETATE			
ROCKAWAY, NJ 07866			
Priority:			
Org Code: 580			
MG			

Application Comment:

FDA Contacts:	ID = 132652		
Project Manager			
Review Chemist	S. POPE	(HFD-580)	301-827-4260
Leader	D. LIN	(HFD-830)	301-827-2003 , Team

Overall Recommendation: ACCEPTABLE on 12-NOV-2003 by J. D AMBROGIO (HFD-322) 301-827-

9049

Establishment: CFN [] FEI []

DMF No: AADA:
Responsibilities: []

Profile: CTL OAI Status: NONE

Estab. Comment: THIS SITE PERFORMS []

Milestone Name Date Type Insp. Date Decision & Reason
Creator

SUBMITTED TO OC 03-NOV-2003
POPES

OC RECOMMENDATION
DAMBROGIOJ

03-NOV-2003

ACCEPTABLE

BASED ON PROFILE

Establishment:

CFN
[
[

FEI]

]

DMF No:

Responsibilities:

[

AADA:

]

Profile:

CTL

OAI Status: NONE

Estab. Comment:
301-827-9049)

FEI [

] (on 12-NOV-2003 by J. D AMBROGIO (HFD-322)

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ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Milestone Name Creator	Date	Type	Insp. Date	Decision & Reason
SUBMITTED TO OC POPES	03-NOV-2003			
SUBMITTED TO DO DAMBROGIOJ	03-NOV-2003	GMP		
DO RECOMMENDATION DAMBROGIOJ	12-NOV-2003			ACCEPTABLE
OC RECOMMENDATION DAMBROGIOJ	12-NOV-2003			BASED ON FILE REVIEW ACCEPTABLE
RECOMMENDATION				DISTRICT

Establishment: CFN 1124535 FEI 1000513101
PHARMACEUTICS INTERNATIONAL LTD
10819 GILRAY RD STE 100
HUNT VALLEY, MD 21030

DMF No: AADA:
Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER

Profile: TCM OAI Status: NONE

EMilestone Name Creator	Date	Type	Insp. Date	Decision & Reason
SUBMITTED TO OC POPES	03-NOV-2003			
SUBMITTED TO DO DAMBROGIOJ	03-NOV-2003	10D		
DO RECOMMENDATION MGARCIAL	03-NOV-2003			ACCEPTABLE
OC RECOMMENDATION DAMBROGIOJ	03-NOV-2003			INSPECTION ACCEPTABLE
RECOMMENDATION				DISTRICT

Establishment: CFN [] FEI []
 DMF No: [] AADA:
 Responsibilities: []
 Profile: CSN OAI Status: NONE

Estab. Comment: THIS ESTABLISHMENT IS LISTED IN DMF [] FOR THE
 []

(on 03-NOV-2003 by S. POPE (HFD-580) 301-827-

4260)

Milestone Name	Date	Type	Insp. Date	Decision & Reason
----------------	------	------	------------	-------------------

CREATOR				
SUBMITTED TO OC	03-NOV-2003			
POPES				
OC RECOMMENDATION	03-NOV-2003			ACCEPTABLE
DAMBROGIOJ				BASED ON PROFILE

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EMilestone Name Creator	Date	Type	Insp. Date	Decision & Reason
SUBMITTED TO OC POPE	03-NOV-2003			
SUBMITTED TO DO DAMBROGIOJ	03-NOV-2003	GMP		
DO RECOMMENDATION DAMBROGIOJ	12-NOV-2003			ACCEPTABLE
OC RECOMMENDATION DAMBROGIOJ	12-NOV-2003			BASED ON FILE REVIEW ACCEPTABLE
RECOMMENDATION				DISTRICT

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On Original**