

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-224

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS**ABBREVIATED NEW DRUG APPLICATION**
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. **CHEMIST REVIEW NO. # 3**
2. **ANDA # 75-224**
3. **NAME AND ADDRESS OF APPLICANT:**

Taro Pharmaceuticals USA Inc.
Attention: Lorraine Sachs
5 Skyline Drive
Hawthorne, NY 10532

4. **LEGAL BASIS OF SUBMISSION:**

Reference Listed Drug: **TEMOVATE® Solution, 0.05%**
Manufacturer: Glaxo Wellcome, Research Triangle Park, NC
NDA # 19-966

(Application# N19966 001; Feb 22, 1990; 0.05% soln)

Taro's proposed drug product contains the same active and inactive ingredients and has the same strength, dosage form, route of administration, indications and usage as that of the listed drug product (v1.1, p11).

The firm has certified in their application that in its opinion and to the best of its knowledge, there are no patents that claim the listed drug referred in this application. Also the reference listed drug is not entitled to any exclusivity provisions (v1.1, fax p002 and p7-9).

5. **SUPPLEMENT(s):** N/A
6. **PROPRIETARY NAME:** N/A
7. **NONPROPRIETARY NAME:**
Clobetasol Propionate Topical Solution USP, 0.05%
8. **SUPPLEMENT(s) PROVIDE(s) FOR:** N/A
9. **AMENDMENTS AND OTHER DATES:**
Applicant:
09-18-98 Facsimile amendment - Response to deficiency letter

of 09/04/98.
 03-23-98 Amendment - Response to deficiency letter of
 02/02/98.
 10-08-97 Original submission date
 11-07-97 Correspondence date

FDA:

11-13-97, ANDA Acceptance letter
 02-02-98 Deficiency letter - Major amendment
 09-04-98 Deficiency letter - Facsimile amendment

Debarment Certification: Included section XIX(v1.1, p578)

10. PHARMACOLOGICAL CATEGORY:

Anti-inflammatory

11. Rx or OTC: Rx

12. RELATED IND/NDA/DMF(s):

Approved NDA 19-966 for innovator

Facility

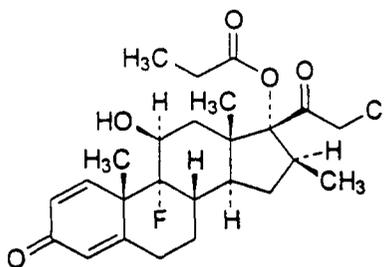
13. DOSAGE FORM: Solution (Topical)

14. STRENGTH: 0.05 %

15. CHEMICAL NAME, STRUCTURE AND PHYSICAL PROPERTIES:

Clobetasol Propionate is a white cream-colored crystalline powder insoluble in water.

Clobetasol Propionate. Pregna-1,4-diene-3,20-dione, 21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (11b,16b)-. $C_{25}H_{32}ClFO_5$. 466.99. 25122-46-7. Anti-inflammatory. USP 23, page 2626 (Second Supplement).



16. COMMENTS:

All sections are Satisfactory.

17. CONCLUSIONS AND RECOMMENDATIONS:

The application is approvable.

18. RECORDS AND REPORTS: N/A

19. REVIEWER: Neeru B. Takiar
Endorsed by P. Schwartz, Ph.D.

DATE COMPLETED: 09/25/98

Page(s)

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Information and are not
releasable.

Chem Rev 3

9/25/98

OFFICE OF GENERIC DRUGSABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMIST REVIEW NO. # 2
2. ANDA # 75-224
3. NAME AND ADDRESS OF APPLICANT:

Taro Pharmaceuticals USA Inc.
Attention: Lorraine Sachs
5 Skyline Drive
Hawthorne, NY 10532

4. LEGAL BASIS OF SUBMISSION:

Reference Listed Drug: TEMOVATE® Solution, 0.05%
Manufacturer: Glaxo Wellcome, Research Triangle Park, NC
NDA # 19-966
(Application# N19966 001; Feb 22, 1990; 0.05% soln)

Taro's proposed drug product contains the same active and inactive ingredients and has the same strength, dosage form, route of administration, indications and usage as that of the listed drug product (v1.1, p11).

The firm has certified in their application that in its opinion and to the best of its knowledge, there are no patents that claim the listed drug referred in this application. Also the reference listed drug is not entitled to any exclusivity provisions (v1.1, fax p002 and p7-9).

5. SUPPLEMENT(s): N/A
6. PROPRIETARY NAME: N/A
7. NONPROPRIETARY NAME:
Clobetasol Propionate Topical Solution USP, 0.05%
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:
Applicant:

03-23-1998: Amendment - Response to deficiency letter of
02/02/98.
10-08-1997: Original submission date
11-07-1997: Correspondence date

FDA:
11-13-1997 ANDA Acceptance letter
02-02-1998 Deficiency letter - Major amendment

Debarment Certification: Included section XIX(v1.1, p578)

10. PHARMACOLOGICAL CATEGORY:

Anti-inflammatory

11. Rx or OTC: Rx

12. RELATED IND/NDA/DMF(s):

Approved NDA 19-966 for innovator

ility

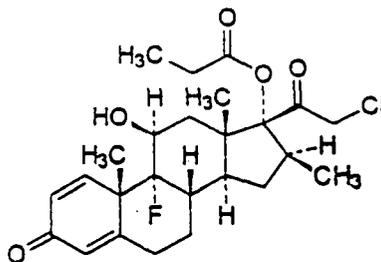
13. DOSAGE FORM: Solution (Topical)

14. STRENGTH: 0.05 %

15. CHEMICAL NAME, STRUCTURE AND PHYSICAL PROPERTIES:

Clobetasol Propionate is a white cream-colored crystalline powder insoluble in water.

Clobetasol Propionate. Pregna-1,4-diene-3,20-dione, 21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (11b,16a)-. $C_{25}H_{31}ClFO_6$: 466.99. 25122-46-7. Anti-inflammatory. USP 23, page 2626 (Second Supplement).



16. COMMENTS:

The following sections are *NOT SATISFACTORY*:

- 23. Raw material - active & inactive ingredients
- 29. Laboratory controls - finished dosage form
- 30. Stability

17. CONCLUSIONS AND RECOMMENDATIONS:

The application is not approvable.

18. RECORDS AND REPORTS: N/A

19. REVIEWER: Neeru B. Takiar
Endorsed by P. Schwartz, Ph.D.

DATE COMPLETED: 07/28/98

Page(s)

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Chem Rev 2
7/28/98

OFFICE OF GENERIC DRUGS**ABBREVIATED NEW DRUG APPLICATION**
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMIST'S REVIEW NO. # 1
2. ANDA # 75-224
3. NAME AND ADDRESS OF APPLICANT:

Taro Pharmaceuticals U.S.A., Inc.,
Attention: Lorraine Sachs
5 Skyline Drive
Hawthorne, NY 10532

4. LEGAL BASIS OF SUBMISSION:

Reference Listed Drug: **TEMOVATE®** Solution, 0.05%
Manufacturer: Glaxo Wellcome, Research Triangle Park, NC
NDA # 19-966
(Application# N19966 001; Feb 22, 1990; 0.05%
soln)

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5. SUPPLEMENT(s): N/A
6. PROPRIETARY NAME: N/A
7. NONPROPRIETARY NAME:
Clobetasol Propionate Topical Solution, USP
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:
Applicant:
10-08-1997 Original submission date

11-07-1997 Correspondence date

FDA:

11-13-1997 ANDA Acceptance letter

Debarment Certification: Included section XIX(v1.1, p578)

10. PHARMACOLOGICAL CATEGORY:

Anti-inflammatory

11. Rx or OTC: Rx

12. RELATED IND/NDA/DMF(s):

Approved NDA 19-966 for innovator

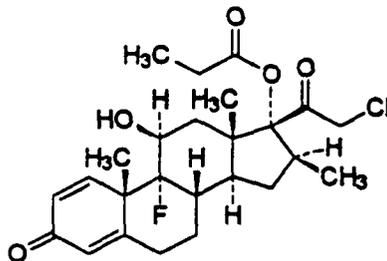
13. DOSAGE FORM: Solution (Topical)

14. STRENGTH: 0.05 %

15. CHEMICAL NAME, STRUCTURE AND PHYSICAL PROPERTIES:

Clobetasol Propionate is a white cream-colored crystalline powder insoluble in water.

Clobetasol Propionate. Pregna-1,4-diene-3,20-dione, 21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (11 β ,16 β)-. C₂₅H₃₂ClFO₅. 466.99. 25122-46-7. Anti-inflammatory. USP 23, page 2626 (Second Supplement).



16. COMMENTS:

The following sections are *NOT SATISFACTORY*:

- 23. Raw material - active and inactive ingredients
- 26. Manufacturing and processing
- 27. container/Closure
- 29. Laboratory controls - (In-process, finished dosage form and method validations)
- 30. Stability
- 35. Environmental Impact considerations/Categorical Exclusion.

The following sections are *PENDING*

- 32. Labeling
- 34. Bioequivalency.

17. CONCLUSIONS AND RECOMMENDATIONS:

The application is not approvable.

18. RECORDS AND REPORTS: N/A

19. REVIEWER: Neeru B. Takiar
Endorsed by P. Schwartz, Ph.D.

DATE COMPLETED: 12/30/97

Page(s)

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Comm Rev 1

12/30/97