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RESEARCH**

APPLICATION NUMBER:

75-390

CHEMISTRY REVIEW(S)

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

NAPROXEN DELAYED-RELEASE TABLETS

1. CHEMISTRY REVIEW NO. 5
2. ANDA # 75-390
3. NAME AND ADDRESS OF APPLICANT

Head Office:

Alphapharm Pty. Ltd.
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
Australia

Manufacturing Site:

Alphapharm Pty. Ltd.
15 Garnet Street
Carol Park QLD 4300
Australia

In the amendment dated December 14, 00, Alphapharm informed of the following change in their agent status.

US Agent:

King and Spalding
Attn: Eugene Pfeifer
1730 Pennsylvania Avenue, N.W.
Washington, D.C. 20006-4706

Telephone: 202/737-0500
Fax: 202/626-3737

4. LEGAL BASIS FOR SUBMISSION

NDA 20-067 (EC-Naprosyn Oral Delayed Release Tablets, 375 mg and 500 mg (Syntex))

Alphapharm certifies that there are neither patent nor any exclusivity entitlement against their application (pages 00010-00011).

(Note: In the amendment dated February 24, 2000, the firm gave EC-NAPROSYN by Roche Laboratories as the reference listed product as the basis for submission.)

5. SUPPLEMENT(s)

Not Applicable.

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Naproxen Tablets,
375 mg and 500 mg Delayed Release Tablets

8. SUPPLEMENT(s) PROVIDE(s) FOR:

Not applicable

9. AMENDMENTS AND OTHER DATES:

5-14-98 Date of Original Submission
6-26-98 Refuse to File Letter (OGD/DLPS)
7-10-98 Amendment to Application
7-31-98 Amendment to Application
9-16-98 Letter, Acceptable for Filing; Date (received)
Acceptable for Filing: August 17, 1998
10-2-98 Amendment to Application (Response to RTF Letter)
7-19-99 Amendment to Application (Firm's response to Review #1)
2-24-00 Amendment to Application (Firm's response to Review #2)
3-29-00 Method validation report/recommendation from Philadelphia
District Lab
5-5-00 Amendment to Application (Response to Review #3)
12-14-00 Minor Amendment (Response to review #3 signed 7-28-00)
2-16-01 Minor Amendment (Response DL dated Feb 2, 01)
3-09-01 Telephone Conversation (Christine Markus)
3-27-01 Telephone Amendment (FAX)

10. PHARMACOLOGICAL CATEGORY

Anti-inflammatory, analgesic, antipyretic

11. Rx or OTC

R

12. RELATED IND/NDA/DMF(s)

1
1
1
1
1
1

13. DOSAGE FORM

Delayed-release Tablet

14. POTENCY

375 mg and 500 mg

15. CHEMICAL NAME AND STRUCTURE

Generic name: Naproxen

Chemical name: 2-Naphthaleneacetic acid, 6-methoxy- α -methyl, (S)-

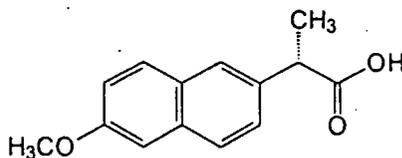
Formula: C₁₄H₁₄O₃

Molecular weight: 230.26

CAS registry number(s): 22204-53-1

Reference: USP 23, page 1053, 2957

Chemical structure:



16. RECORDS AND REPORTS

None

17. COMMENTS

Only most important information is retained in this review. Please see previous reviews for additional information.

On March 27, 01 the firm sent a FAX in response to telephone request concerning dissolution specification. This review is about firm's FAX amendment (Part A) and minor amendment (Part B).

18. CONCLUSIONS AND RECOMMENDATIONS

Approvable

19. REVIEWER:

Raj Bykadi, Ph.D.

DATE COMPLETED:

March 30, 2001

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev 5

3/30/01