CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74931

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 74-931

3. NAME AND ADDRESS OF APPLICANT
Novopharm Limited
30 Nably Court
Scarborough, Ontario
Canada M1B 2K9

U.S. Agent
Granutec, Inc.
Attention: Therese M. Ast
409 Airport Drive N.W.
Wilson, NC 27896

4. LEGAL BASIS FOR SUBMISSION
Expired Patent for NUPRIN®

5. SUPPLEMENT(s)
N/A

6. PROPRIETARY NAME
N/A

7. NONPROPRIETARY NAME
Ibuprofen Tablets USP

8. SUPPLEMENT(s) PROVIDE(s) FOR:
N/A

9. AMENDMENTS AND OTHER DATES:
Original Application Submission Date July 31, 1996
Minor Amendment Date June 27, 1997 (This Review).

10. PHARMACOLOGICAL CATEGORY
Analgesic

11. Rx or OTC
OTC

12. RELATED IND/NDA/DMF(s)
See Section 37

13. DOSAGE FORM
Tablets

14. POTENCY
200 mg

15. CHEMICAL NAME AND STRUCTURE
Chemical Name: ∝-methyl-4-(2-methylpropyl) benzene acetic acid
Structure: As in USP 23

16. RECORDS AND REPORTS
N/A

17. COMMENTS
See individual review sections; comments from the deficiency letter (in bold) are followed by the firm's response.

18. CONCLUSIONS AND RECOMMENDATIONS
Application is Approvable.

19. REVIEWER:
U. S. Atwal

DATE COMPLETED:
July 24, 1997

cc: ANDA 74-931
DUP Jacket
Division File
Field Copy

Endorsements:
HFD-623/U. Atwal, Ph.D./ /S/ 7/25/97
HFD-623/V. Sayeed, Ph.D./ 7/28/97
X:\NEW\FIRMSNZ\NOVOPHARM\LTRS&REV\74931.RV2
F/T by:

ANDA **74-931** APPROVAL SUMMARY

DRUG PRODUCT: Ibuprofen Tablets, USP

FIRM: Novopharm Limited

DOSAGE FORM: Tablet (Round and Capsule-Shaped)

Strength: 200 mg

cGMP STATEMENT/EIR UPDATE STATUS: EER Acceptable Date 01/23/97

BIO STUDY: APPROVE, Letter Sent on 01/02/1997

VALIDATION: DS and DP are compendial

STABILITY: Three months accelerated, 40°C/75%, RH stability data in the smallest and the largest package size, provided. The container/closure systems used for the stability study are equivalent to the systems proposed for commercial use. All reported data are within specifications as listed. Thus, a 24 month expiration date is justified.

Tests and specifications for the drug product on stability include appearance, assay (%), dissolution (NLT % in minutes), water (NMT %), and impurities (any individual NMT %, unknown NMT %, and total known & unknown NMT %).

LABELING: APPROVE, Review Dated 7/16/1997.

STERILIZATION VALIDATION (IF APPLICABLE): N/A

SIZE OF BIO BATCH: The bio batch, lot #3014PD, is one of the two test batches (lot #3014PD & 3016PD). The DS manufacturer is DMF is adequate as of June 11, 1996.

Strength	Test Batch Size
200 mg (capsule shaped)	Tablets (bio batch)
200 mg (round)	Tablets

SIZE OF STABILITY BATCHES: Stability batches are the same as the test batches.

PROPOSED PRODUCTION BATCHES:

Strength	Production Batch Size
200 mg	Tablets

The proposed production manufacturing process is the same as that used for the stability batches.

CHEMIST: /S/ DATE: 8/4/97

SUPERVISOR: DATE: