

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-920

CHEMISTRY REVIEW(S)



NDA 21-920

Naproxen Sodium Capsules

Banner Pharmacaps Inc.

Rao Puttagunta, Ph.D.

Branch III/Pre-Marketing Assessment Division II

Office of New Drug Quality Assessment

Center for Drug Evaluation and Research



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Chemistry Review Data Sheet

1. NDA #: 21-920
2. REVIEW #: 1
3. REVIEW DATE: 12-JAN-2006
4. REVIEWER: Rao Puttagunta, Ph.D.
5. PREVIOUS DOCUMENTS: N/A
6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original	15-APR-2005
Amendment (BC)	29-JUL-2005
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Amendment (BC)	04-JAN-2006
Amendment (BC)	05-JAN-2006

7. NAME & ADDRESS OF APPLICANT:

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Representative: Shelly K. Meachum
Director, Regulatory Affairs
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8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: N/A
- b) Non-Proprietary Name (USAN): Naproxen Sodium Capsules
- c) Code Name/# (ONDC only): N/A
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 3
 - Submission Priority: S

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