

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40199

CHEMISTRY REVIEW(S)

ANDA APPROVAL SUMMARY

DA: 40-199 DRUG PRODUCT: Oxycodone and Acetaminophen Capsules, USP.

FIRM: Amide Pharmaceutical, Inc. DOSAGE FORM: Capsule

STRENGTH: 5 mg/500 mg.

CGMP STATEMENT/EIR UPDATE STATUS:

CGMP certification is satisfactory (See Page 210).

EIR update : Acceptable on May 29, 1997. Update is pending.

BIO STUDY: Satisfactory.

The waiver of in vivo Bioequivalence study for the Oxycodone Acetaminophen Capsules, 5 mg/500 mg, (lot#6069A) is granted. (see Bio. Review by Lin-Whei Chuang on 10-28- 1996).

VALIDATION - (DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):

Not required. This is USP product.

STABILITY - ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN
CONTAINER SECTION?:

Containers used in the stability testing are the same as described in
e container section.

Proposed market container/closures:

Container/closure system for 100's:

Bottle: 150cc, round HDPE bottle

Manufacturer:

Resin:

Colorant:

Cap: 38 mm white metal liner

Manufacturer:

Heat seal:

Coil: rayon

Container/closure system for 1000's:

Bottle: 1500 cc, white HDPE bottle

Manufacturer:

Resin:

Colorant:

Cap: 70 mm white metal liner

Manufacturer:

Coil: rayon

LABELING:

Satisfactory per A. Vezza on August 4, 1998.

STERILIZATION VALIDATION (IF APPLICABLE):

NA

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):

Lot # 6069A

Firm's source of NDS OK : Yes

DMF#

DMF#

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH, WERE THEY
MANUFACTURED VIA THE SAME PROCESS?):

Executed batch: Lot # 6069A : capsule

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS
BIO/STABILITY?:

Proposed production batch: capsules
capsules
capsules

Manufacturing process is the same as bio.stability.

Reviewer: S.Basaran

/S/

for

DATE:11-25-1998

Team Leader: U.Venkataram

/S/

DATE:11-³⁰~~7~~-1998

ADDENDUM TO REVIEW

ANDA: 40-199

Applicant: Amide Pharmaceuticals

Product: Oxycodone + APAP Capsules U.S.P., 5/500 mg

The applicant submitted a telephone amendment, per our request, withdrawing as an outside testing lab. They have included the following new facility:

Functions: OVI, Lead, Arsenic, and Conductivity on inactive raw materials.

A cGMP certification and LOA to reference DMF is included.

Satisfactory

Ubrani V. Venkataram

12/22/98

1 ✓ CHEMISTRY REVIEW NO #3

2. ANDA 40-199 (5 mg/500 mg)

NAME AND ADDRESS OF APPLICANT

Amide Pharmaceuticals, Inc.
Attention: Jasmine Shah
101 East Main Street
Little Falls, Nj 07424

4. LEGAL BASIS FOR SUBMISSION

Tylox Capsules- McNeil Pharmaceuticals
Expired and no patent information; no exclusivity
This ANDA was submitted under section 505 (b) of the act where the Agency determined that the referenced product was suitable for submission as an ANDA.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Oxycodone and Acetaminophen Capsules, USP

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

N/A

9. AMENDMENTS AND OTHER DATES:

Firm:

July 9, 1996: Original submission.
July 9, 1996: New correspondence
March 9, 1998: Amendment
October 26, 1998: Facsimile amendment
November 23, 1998: Telephone amendment

FDA:

August 19, 1996: Acknowledgement letter.
October 31, 1996: Bioequivalence acceptable letter.
March 3, 1997: Deficiency letter
October 9, 1998: Facsimile deficiency letter

10. PHARMACOLOGICAL CATEGORY

Narcotic analgesic

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF#

DMF#

DMF#

DMF#

DMF#

DMF#

DMF#

DMF#

DMF#

DOSAGE FORM

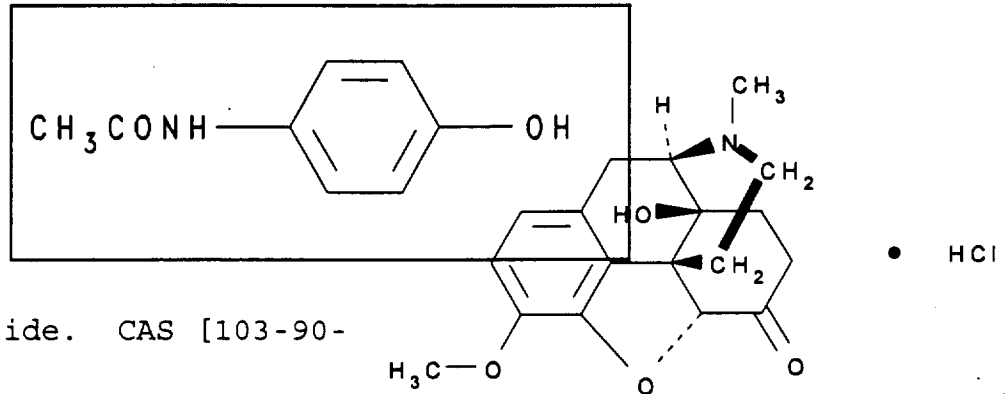
Capsules

14. POTENCY

5 mg/500 mg

15. CHEMICAL NAME AND STRUCTURE

Acetaminophen USP

 $C_8H_9NO_3$; M.W. = 151.16

Oxycodone Hydrochloride USP

 $H_{21}NO_4 \cdot HCl$; M.W. = 351.834,5 α -Epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride.
CAS [124-90-3]16. RECORDS AND REPORTS

Memo of Teleconference between FDA and Amide Pharm on 8-6-96.

17. COMMENTSThe application is satisfactory in CMC, labeling, bio, and MV.
Approval pending acceptable EER update.18. CONCLUSIONS AND RECOMMENDATIONS

The application can be approved upon receipt of an acceptable EER.

19. REVIEWER: _____ DATE COMPLETED: _____

Sema Basaran, Ph.D.

11-25-98