

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
74-974

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620
Microbiologist's Review #2
March 10, 1998

2.1

Golman

A. 1. ANDA: ~~74-974~~

APPLICANT: Taylor Pharmaceuticals (an Akorn Co.)
Attention: James G. Baumann, Jr.
Post Office Box 1220
Decatur, Illinois 62525

2. PRODUCT NAME: **Lorazepam Injection, USP**

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: **0.2% (2 mg/mL)**
Sterile nonpyrogenic solution for intramuscular and
intravenous injection; packaged as a 1 mL fill in a 2.25 mL
glass syringe

4. METHOD(S) OF STERILIZATION:

5. PRINCIPLE INDICATIONS: Used as a preanesthetic medication
in adult patients to produce sedation, relief of anxiety
and decreased ability to recall events related to the day
of surgery

6. PHARMACOLOGICAL CATEGORY: Anti-anxiety drug

B. 1. DATE OF INITIAL SUBMISSION: October 1, 1996
(Received by OGD on October 4, 1996)

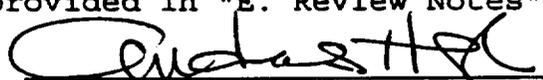
2. DATE OF AMENDMENT: August 15, 1997
Subject of this Review (Received by OGD on August 21, 1997)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: 3/9/98

C. REMARKS: The subject amendment is in response to the
microbiology deficiencies in the letter dated June
12, 1997.

D. CONCLUSIONS: The submission is recommended for approval on
the basis of sterility assurance. Specific
comments are provided in "E. Review Notes".

 3/16/98
Andrea S. High, Ph. D.

cc:

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Information and are not

releasable.

micro Rev. #2

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