

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

74-974

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 3
2. ANDA # 74-974 (1 mL/2.25 mL syringe)

3. NAME AND ADDRESS OF APPLICANT

Taylor Pharmaceuticals (Formerly Akorn, Inc.)
 Attention: James G. Baumann, Jr.
 P.O. Box 1220
 Decatur, IL 62525

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4. LEGAL BASIS FOR SUBMISSION

The RLD is Ativan®, Wyeth-Ayerst, NDA 18-140. There is no unexpired patent and no marketing exclusivity.

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|-------------------------------|---|
| 5. <u>SUPPLEMENT(s)</u> | 6. <u>PROPRIETARY NAME</u> |
| N/A | None |
| 7. <u>NONPROPRIETARY NAME</u> | 8. <u>SUPPLEMENT(s) PROVIDE(s) FOR:</u> |
| Lorazepam Injection, USP | N/A |

9. AMENDMENTS AND OTHER DATES:

Original ANDA	October 1, 1996
Deficiency Letter	June 12, 1997
Amendment	August 15, 1997
Amendment	August 20, 1997
Amendment	March 2, 1998
Amendment	June 9, 1998
Amendment	July 7, 1998

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|-------------------------------------|----------------------|
| 10. <u>PHARMACOLOGICAL CATEGORY</u> | 11. <u>Rx or OTC</u> |
| Preanesthetic anxiolytic agent | Rx |

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM

Injection solution

14. STRENGTH

Lorazepam

0.2% (2 mg/mL, 1 mL/2.25 mL syringe)

15. CHEMICAL NAME AND STRUCTURE

Name: Lorazepam

Chemical name: 2H-1,4-Benzodiazepin-2-one, 7-chloro-5-(2-chlorophenyl)-1,3-dihydro-3-hydroxy-, (±)-

CAS number: 846-49-1

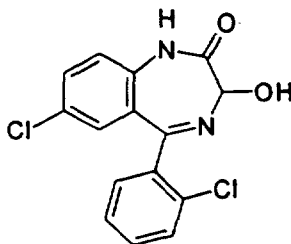
Molecular weight: 321.16

Chemical formula: $C_{15}H_{10}Cl_2N_2O_2$

Pharmacologic/therapeutic category: Tranquilizer (minor)

Reference: USP 23, page 903

Structural formula:

16. RECORDS AND REPORTS N/A17. COMMENTS

The application was found approvable.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

Kathy P. Woodland

DATE COMPLETED:

7/8/98

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Contain Trade Secret,

Commercial/Confidential

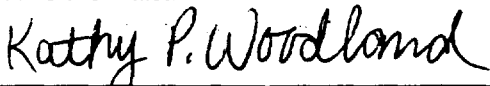
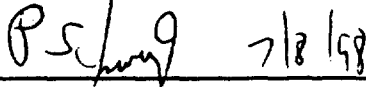
Information and are not

releasable.

Chen Rev 3

7/8/98

ANDA APPROVAL SUMMARY

ANDA: 74-974	CHEMIST: Kathy P. Woodland	DATE: July 8, 1998
DRUG PRODUCT: Lorazepam Injection, USP		
FIRM: Taylor Pharmaceuticals (Formerly Akorn, Inc.)		
DOSAGE FORM: Injection	STRENGTH: 0.2% ,2mg/mL (1 ml/2.25 ml syringe)	
cGMP: Satisfactory June 24, 1997.		
BIO: Satisfactory, Reviewed by Moo Park , Ph.D., on April 15, 1998.		
VALIDATION - (Description of dosage form same as firm's): USP drug substance and product.		
STABILITY: The containers in the stability studies are identical to those in the container section.		
LABELING: Approved by L. Golson on May 26, 1998.		
STERILIZATION VALIDATION (If applicable): Aseptic processing approved by Andrea High, Ph.D., March 16, 1998		
SIZE OF BIO BATCH (Firm's source of NDS ok?): Waiver granted.		
SIZE OF STABILITY BATCHES (If different from bio batch, were they Manufactured via the same process?): The exhibit batch was 20 L.		
PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME?: The proposed production batches are 36 L, 48 L and 100 L.		
Signature of chemist: 	Signature of supervisor:  7/8/98	

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