

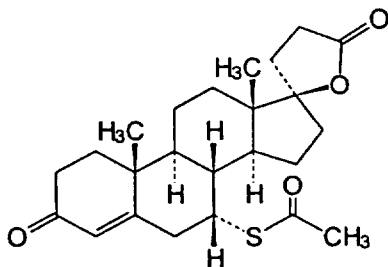
**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40-424

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO: 2/3
2. ANDA: 40-424
3. NAME AND ADDRESS OF APPLICANT:
Mylan Pharmaceuticals Inc.
Attention: Frank Sisto
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310
Telephone: 304-599-2595
Facsimile: 304-285-6407
4. LEGAL BASIS for ANDA SUBMISSION: See Chemistry Review #1
5. SUPPLEMENT(s): N/A
6. PROPRIETARY NAME: N/A
7. NONPROPRIETARY NAME: Spironolactone Tablets USP
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:
Original Submission: 11/13/00
Amendment: 4/27/01
Amendment: 5/10/01
Telephone Amendment: 6/25/01
Amendment: 6/27/01
Telephone Amendment: 7/27/01
10. PHARMACOLOGICAL CATEGORY: Diuretic
11. OTC/R_x: R_x
12. RELATED IND/NDA/DMF(s): See DMF Checklist
13. DOSAGE FORM: Coated Tablets
14. STRENGTH: 25 mg, 50 mg, and 100 mg
15. CHEMICAL NAMES AND STRUCTURE:
Pregn-4-ene-21-carboxylic acid; 7-(acetylthio)-17-hydroxy-3-oxo-, γ-lactone, (7α,17α)-; C₂₄H₃₂O₄S; MW = 416.59.
CAS #52-01-7; Diuretic; Aldosterone Antagonist.



16. RECORDS AND REPORTS: N/A

17. COMMENTS: **This reviewer feels that some of the data used to support this ANDA may be suspect (see stability section of this review).**

18. CONCLUSIONS AND RECOMMENDATIONS: **Approvable**

19. REVIEWER: ARaw

DATE COMPLETED: 6/07/01

Revised (Telephone Amendments): 8/01/01

cc: .

Endorsements:

*ARaw 8/14/01
K01*

Page(s) 20

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Commercial/Confidential
Information and are not
releasable.

Chen Rev 1

6/7/01