

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-228/S-003**

**CHEMISTRY REVIEW(S)**

**CHEMIST'S REVIEW #1  
OF SUPPLEMENT**

- 1. ORGANIZATION:** DRUDP HFD-580
- 2. NDA NUMBER:** 21-228
- 3. SUPPLEMENT NUMBER/DATES:** SCM-003  
Letterdate: 7-NOV-2001  
Stampdate: 13-NOV-2001
- 4. AMENDMENTS/REPORTS/DATES:**
- 5. RECEIVED BY CHEMIST:** 16-NOV-2001

**6. APPLICANT NAME AND ADDRESS:**

Pharmacia & Upjohn Co.  
7000 Portage Road  
Kalamazoo MI 49001

**7. NAME OF DRUG:**

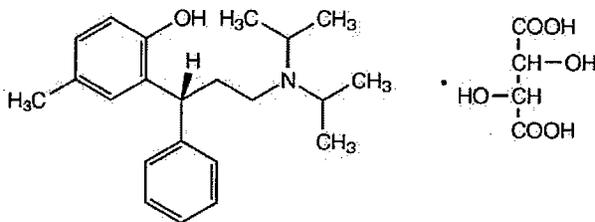
Detrol LA

**8. NONPROPRIETARY NAME:**

Tolterodine tartrate extended release capsules

**9. CHEMICAL NAME/STRUCTURE:**

(R)-N,N-diisopropyl-3-(2-hydroxy-5-methylphenyl)-3-phenylpropanamine L-hydrogen tartrate



**10. DOSAGE FORM(S):**

extended release capsules

**11. POTENCY:**

2 mg and 4 mg

**12. PHARMACOLOGICAL CATEGORY:**

Treatment of overactive bladder

**13. HOW DISPENSED:**

Rx

**14. RECORDS & REPORTS CURRENT:**

None

**15. RELATED IND/NDA/DMF:**

None

**16. SUPPLEMENT PROVIDES FOR:**

An alternate primary packaging and labeling site at the address : \_\_\_\_\_  
\_\_\_\_\_

**17. COMMENTS:**

- A written certification stating that the proposed alternate packaging site is in conformance with cGMPs.
- A commitment to place the first production lot of each strength packaged in each container/closure configuration on long-term stability using the approved protocol. In addition, one lot per year of each strength will also be placed on stability.
- CDER Compliance recommends "Acceptable" for the proposed alternate packaging site on 5-DEC-2001 (report is attached).
- There is no other change to the NDA associated with this supplement. All packaging materials are the same as those currently approved.

**18. CONCLUSIONS AND RECOMMENDATIONS:**

All information provided in the supplement SCM 003 is satisfactory. Please issue an APPROVAL letter for this supplement.

**19. REVIEWER NAME**

Suong T. Tran, Ph.D.

**SIGNATURE**

**DATE COMPLETED**

cc:

Original: NDA 21-228

HFD-580/Division File

HFD-580/EFarinas

HFD-580/STran/MJRhee

INIT by MJ Rhee

Filename: 21228 SCM003.doc

**APPEARS THIS WAY  
ON ORIGINAL**