

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-228/S-002

CHEMISTRY REVIEW(S)

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

- 1. ORGANIZATION:** DRUDP HFD-580
- 2. NDA NUMBER:** 21-228
- 3. SUPPLEMENT NUMBER/DATES:** SLR-002
Letterdate: 06-JUL-2001
Stampdate: 06-JUL -2001
- 4. AMENDMENTS/REPORTS/DATES:**
- 5. RECEIVED BY CHEMIST:** 10-AUG-2001

6. APPLICANT NAME AND ADDRESS:

Pharmacia & Upjohn Co.
7000 Portage Road
Kalamazoo MI 49001

7. NAME OF DRUG:

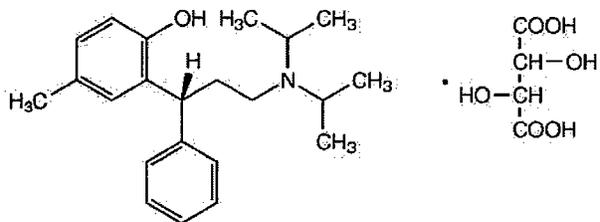
Detrol LA

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:

Change in the Description of the package insert – to delete “ammonium hydroxide” from the list of inactive ingredients.

17. COMMENTS:

- Ammonium hydroxide is used in the manufacture of _____
- The deletion of “ammonium hydroxide” from the list of inactive ingredients in the Description of the package insert is acceptable. Ammonium hydroxide is not part of the ingredients remaining in the final form of the drug product.

18. CONCLUSIONS AND RECOMMENDATIONS:

All information provided in the supplement SLR 002 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 SLR002.doc

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/s/

Suong Tran
8/23/01 03:10:51 PM
CHEMIST

your paper sign-off 8/14

Moo-Jhong Rhee
8/23/01 04:33:08 PM
CHEMIST
I concur

**APPEARS THIS WAY
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