

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

76-151

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 1

2. ANDA # 76-151

3. NAME AND ADDRESS OF APPLICANT

Torpharm

50 Steinway Boulevard

Etobicoke, Ontario

M9W 643

Canada

US Agent for Torpharm

Apotex Corporation

Attention: Marcy MacDonald

50 Lakeview Parkway

Vernon Hills, IL 60061

4. LEGAL BASIS FOR SUBMISSION

The reference listed drug is Cardizem CD Capsules.

5. SUPPLEMENT (s) N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Diltiazem Hydrochloride

8. SUPPLEMENT (S) PROVIDE (S) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

Original Submission 03/27/01

Refuse to File 04/27/01

Amendment 07/30/01

Ack Ltr 09/24/01

Amendment

78/29/05

Jan 1/25/02

10. PHARMACOLOGICAL CATEGORY

Anti-Hypertensive

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM

ER Capsule

14. POTENCIES

120 mg; 180 mg; 240 mg; 300 mg

15. CHEMICAL NAME AND STRUCTURE

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

Not approvable - Minor

19. REVIEWER:

A. Langowski

DATE COMPLETED:

10/30/01

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commercial

information

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confidential

commercial

information

1. CHEMISTRY REVIEW NO. 3
2. ANDA # 76-151
3. NAME AND ADDRESS OF APPLICANT
Torpharm
50 Steinway Boulevard
Etobicoke, Ontario
M9W 6Y3
Canada
US Agent for Torpharm
Apotex Corporation
Attention: Marcy MacDonald
50 Lakeview Parkway
Suite #127
Vernon Hills, IL 60061
4. LEGAL BASIS FOR SUBMISSION
The reference listed drug is Cardizem CD Capsules.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME
Dilt CD
7. NONPROPRIETARY NAME
Diltiazem Hydrochloride
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:

Original Submission	03/29/01
Refuse to File	04/27/01
Amendment	08/29/01
Ack Ltr	09/24/01
Amendment	02/26/02
Amendment	10/21/02
Amendment	01/24/03
Amendment	03/03/03
10. PHARMACOLOGICAL CATEGORY
Anti-Hypertensive
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
ER Capsule
14. POTENCIES
120 mg; 180 mg; 240 mg; 300 mg
15. CHEMICAL NAME AND STRUCTURE
1,5-Benzothiazepin-4(5H)-one, 3-(acetyloxy)-5-[2-dimethyl-amino)ethyl]2,3-dihydro-2-(4-methoxyphenyl)-onohydrchloride
(+)cis
17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS
NA Minor

19. REVIEWER: DATE COMPLETED:
A.Langowski 1/2/03, 5/6/03

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1. CHEMISTRY REVIEW NO. 4
2. ANDA # 76-151
3. NAME AND ADDRESS OF APPLICANT
US Agent for Torpharm
Apotex Corporation
Attn: Marci MacDonald
616 Heathrow Drive
Lincolnshire, IL 60069
4. LEGAL BASIS FOR SUBMISSION
The reference listed drug is Cardizem CD Capsules.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME
Dilt CD
7. NONPROPRIETARY NAME
Diltiazem Hydrochloride
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES:
- | | |
|---------------------|----------|
| Original Submission | 03/29/01 |
| Refuse to File | 04/27/01 |
| Amendment | 08/29/01 |
| Ack Ltr | 09/24/01 |
| Amendment | 02/26/02 |
| Amendment | 10/21/02 |
| Amendment | 01/24/03 |
| Amendment | 03/03/03 |
| Amendment | 4/12/03 |
| NA Ltr | 05/12/03 |
| Amendment | 10/20/03 |
| Amendment | 04/14/04 |
10. PHARMACOLOGICAL CATEGORY
Anti-Hypertensive
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
ER Capsule
14. POTENCIES
120 mg; 180 mg; 240 mg; 300 mg

15. CHEMICAL NAME AND STRUCTURE
1,5-Benzothiazepin-4(5H)-one, 3-(acetyloxy)-5-[2-dimethyl-amino)ethyl]2,3-dihydro-2-(4-methoxyphenyl)-onohydrchloride
(+) cis
17. COMMENTS N/A
18. CONCLUSIONS AND RECOMMENDATIONS
Approve
19. REVIEWER: DATE COMPLETED:
A.Langowski 04/19/04

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