

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-138

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO 2~~7~~

2. ANDA 75-138

3. NAME AND ADDRESS OF APPLICANT

Mylan Pharmaceuticals, Inc.
Attention: Frank R. Sisto
781 Chestnut Ridge Rd.
P. O. Box 4310
Morgantown WV 26504-4310

4. LEGAL BASIS FOR SUBMISSION

The Division of Bioequivalence has determined on 6/11/97 that the study submitted by Mylan satisfies the regulatory requirements of "completeness" so the ANDA 75-138 may be filed and that a period of six months of market exclusivity can be granted to the applicant who submitted the first substantially complete ANDA under 21 USC 355 (j)(4)(B)(iv).

Mylan's patent certification/exclusivity statement is presented (p. 8). Mylan states that it will market the drug product upon approval of the application and resolution of the validity, enforcement, or infringement of patent number 4,863,742 (American Cyanamid Co. and Elan Corporation, PLC.) that expires on June 19, 2007.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Verapamil Hydrochloride Extended-Release Capsules

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original submission-	May 28, 1997
FDA acknowledgment--	July 29, 1997
Amendment--	December 31, 1997 (120 & 180 mg)
Deficiency--	March 6, 1998
Amendment--	May 22, 1998
Amendment--	December 14, 1998

10. PHARMACOLOGICAL CATEGORY

Management of hypertension
Calcium ion influx inhibitor

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

i
483) & Opacode Black
lorcon

13. DOSAGE FORM 14. POTENCY
EXC (Extended-release Capsules) 120 mg, 180 mg & 240 mg

15. CHEMICAL NAME AND STRUCTURE
Verapamil Hydrochloride USP

$C_{27}H_{38}N_2O_4 \cdot HCl$; M.W. = 491.07

16. RECORDS AND REPORTS
The amendment dated December 31, 1997 added the 120 mg and 180 dosage strengths. Chemistry data and a bio data (dissolution profiles and waiver request) are included.

17. COMMENTS
N/A

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend approval letter to issue.

19. REVIEWER: DATE COMPLETED:
A. Croitoru January 22, 1999
Edwin Ramos February 5, 1999 (revised)



2/8/99

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem. Rev 2

2/8/99