

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19787/S016

CHEMISTRY REVIEW(S)

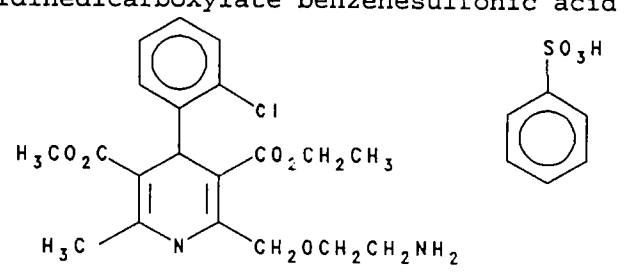
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NDA 19-787

PFIZER

NORVASC

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-787
3. Name and Address of Applicant (City & State) Pfizer, Inc. 235 East 42nd Street New York, NY 10017-5755		4. Supplement(s) Number(s) S-016 Date(s) 01-20-98	
5. Drug Name NORVASC	6. Nonproprietary Name Amlodipine Besylate		8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: an alternate purification process using amlodipine besylate drug substance synthesis.			
9. Pharmacological Category Antihypertensive and Antianginal	10. How Dispensed ☒ RX ☐ OTC	11. Related IND(s)/ NDA(s)/DMF(s)	
12. Dosage Form(s) Tablet	13. Potency(ies) 2.5, 5, and 10 mg		
14. Chemical Name and Structure 3-Ethyl-5-methyl-2-(2-aminoethoxymethyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl-3,5-pyridinedicarboxylate benzenesulfonic acid		15. Records/Reports Current	
		☒ Yes ☐ No Reviewed ☒ Yes ☐ No	
16. Comments:			
17. Conclusions and Recommendations: Satisfactory and approval letter is being sent.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature <i>/S/</i>		Date Completed 03/03/98
19. Distribution: ☒ Original Jacket ☐ Reviewer ☐ Division File ☐ CSO			

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3/5/98