

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-735 / S-008

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW		1. ORGANIZATION DAIDP (HFD-520)	2. NDA NUMBER 19-735
3. NAME & ADDRESS OF APPLICANT R.W. Johnson Pharmaceutical Research Institute Route 202, P.O. Box 300 Raritan, New Jersey 08869		4. AF NUMBER	
5. SUPPLEMENT(s) NUMBER(s) DATE(s)			
6. NAME OF DRUG Floxin	7. NONPROPRIETARY NAME ofloxacin	S-008 1/31/92	
8. SUPPLEMENT(s) PROVIDES FOR: Changes in the control procedures for the acceptance of the new drug substance.		9. AMENDMENTS AND OTHER (REPORTS, etc.) DATES	
10. PHARMACOLOGICAL CATEGORY Antibacterial	11. HOW DISPENSED XXX Rx OTC	12. RELATED IND/NDA/DMF(s)	
13. DOSAGE FORM(s) Tablet	14. POTENCY(ies) 200, 300 and 400 mg		
15. CHEMICAL NAME AND STRUCTURE			
16. RECORDS AND REPORTS			
CURRENT			
Yes No			
REVIEWED			
Yes No			
17. COMMENTS			
18. CONCLUSIONS AND RECOMMENDATIONS Approval letter should be issued by the Supervisory Chemist.			
cc: Orig: NDA 19-735/S-008 HFD-520 HFD-520/MO/Szarfman HFD-520/Pharm/LBuko HFD-520/CSO/PFogarty HFD-520/CHEM/BVShetty/th/6/23/92 R/D initialed by SUPVCHEM/6/22/92			
19. NAME B. Vithal Shetty, Ph.D.		REVIEWER SIGNATURE <i>BVShetty</i>	DATE COMPLETED 6/23/92 6/17/92
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