

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-735 / S-001

CHEMISTRY REVIEW(S)

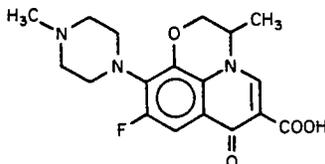
NDA SUPPLEMENT REVIEW
CHEMISTRY - #1

FEB 17 1991

1. Division of Anti-Infective Drug Products (DAIDP)
2. NDA NUMBER: 19-735
3. NAME AND ADDRESS OF APPLICANT (CITY AND STATE):
The R. W. Johnson Pharmaceutical Research Institute
Route 202, P.O. Box 300
Raritan, NJ 08869-0602
4. DATE APPLICATION APPROVED: 12-31-90
5. SUPPLEMENT(S) (NUMBER AND DATE):
SCS-001
dated: January 21, 1991
received: January 22, 1991
assigned: January 24, 1991
6. NAME OF DRUG: FLOXIN
7. NONPROPRIETARY NAME: ofloxacin
8. SUPPLEMENT(S) PROVIDE(S) FOR: Revisions to the Chemistry, Manufacturing and Control section of the application.

"Special Supplement Changes Being Effected"
9. AMENDMENTS AND OTHER DATES (Reports, etc.):
None indicated
10. PHARMACOLOGICAL CATEGORY: Quinolone antibacterial
11. HOW DISPENSED: Rx
12. SUPPORTING OR RELATED IND(s)/NDA(s)/DMF(s):
Not applicable
13. DOSAGE FORM: Film coated tablets
14. POTENCY: 200mg, 300mg and 400mg
15. CHEMICAL NAME AND STRUCTURE (re: USAN):

Ofloxacin [1984] (oh floks' a sin). $C_{18}H_{20}FN_3O_4$. 361.37. (1) 7*H*-Pyrido[1,2,3-*de*]-1,4-benzoxazine-6-carboxylic acid, 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-, (\pm)-; (2) (\pm)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7*H*-pyrido[1,2,3-*de*]-1,4-benzoxazine-6-carboxylic acid. CAS-82419-36-1. INN; BAN. *Antibacterial*. (Daiichi Seiyaku, Japan); Oflox (Allergan); component of Ortho-Cyclen (Ortho Pharmaceutical) \blacklozenge DL-8280; HOE 280



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Chemistry Review

18. **CONCLUSIONS AND RECOMMENDATIONS:**

The outlined chemistry, manufacturing and control changes are acceptable. Approve S-001 . Approval letter to issue.

cc: Orig NDA

HFD-520

HFD-520/MO/szarfman

HFD-520/Sup.Chem/DeCamp *WS 2/17/91*

HFD-520/Pharm/buko

HFD-520/CSO/fogarty

19. **REVIEWER**

Mary Ann Jarski

Mary Ann Jarski 2/14/91

Date Completed

February 14, 1991