

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-277

CHEMISTRY REVIEW(S)



Chemistry Review Data Sheet

1. NDA 21-277
2. REVIEW #: 1
3. REVIEW DATE: 11/26/01
4. REVIEWER: Dorota Matecka
5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
Original	11/2/00
Amendment (BC)	5/8/01
Amendment (BC)	6/13/01
Amendment (AC)	7/3/01
Amendment (BC)	8/30/01
IR letter	11/19/01
Amendment (BC)	11/20/01

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original	11/2/00
Amendment (BC)	5/8/01
Amendment (BC)	6/13/01
Amendment (AC)	7/3/01
Amendment (BC)	8/30/01
Amendment (BC)	11/20/01



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7. NAME & ADDRESS OF APPLICANT:

Name:	Bayer Corporation Pharmaceutical Division
Address:	400 Morgan Lane, West Haven, CT 06516
Representative:	Andrew Verderame, Associate Director, Regulatory Affairs
Telephone:	(203) 812-5172

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: AVELOX I.V.
- b) Non-Proprietary Name (USAN): moxifloxacin hydrochloride in sodium chloride injection
- c) Code Name/#: BAY 12-8039 (moxifloxacin hydrochloride)
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: N/A

10. PHARMACOL. CATEGORY: Antibacterial

11. DOSAGE FORM: intravenous solution

12. STRENGTH/POTENCY: 0.16% (400 mg)

13. ROUTE OF ADMINISTRATION: intravenous

14. Rx/OTC DISPENSED: Rx OTC

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product



CHEMISTRY REVIEW

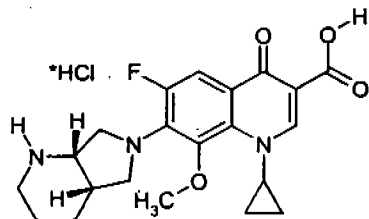


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16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Moxifloxacin Hydrochloride, $C_{21}H_{24}N_3FO_4 \times HCl$, MW = 437.9

Monohydrochloride salt of 1-cyclopropyl-7-[(S,S)-2,8-diazabicyclo[4.3.0]non-8-yl]-6-fluoro-8-methoxy-1,4-dihydro-4-oxo-3-quinoline carboxylic acid



17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	COD E ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
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¹ Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 – Type 1 DMF

3 – Reviewed previously and no revision since last review

4 – Sufficient information in application

5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)



CHEMISTRY REVIEW



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B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
NDA	21-085	AVELOX Tablets
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18. STATUS:

CONSULTS/ CMC RELATED REVIEWS	RECOMMENDATION	DATE	REVIEWER
EES	Acceptable	10/22/01	N/A
OPDRA	Acceptable	4/26/01	Carol Holquist, R.Ph.
EA	Categorical exclusion	N/A	N/A
Microbiology	Acceptable	10/17/01	Vinnie Pawar, Ph.D.

**APPEARS THIS WAY
ON ORIGINAL**

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