

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40-274

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 40-274

3. NAME AND ADDRESS OF APPLICANT

Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310
(304) 599-2595

4. LEGAL BASIS FOR SUBMISSION

Plaquenil Sulfate (Sanofi Winthrop Pharmaceuticals)

Mylan certifies that to the best of their knowledge that there are no patents and the product is not covered by any exclusivity provisions.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Hydroxychloroquine Sulfate

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

N/A

9. AMENDMENTS AND OTHER DATES:

Amendment September 19, 1997
Correspondence February 27, 1998
Amendment April 1, 1998

10. PHARMACOLOGICAL CATEGORY

Antimalarial, suppressant
(lupus erythematosus).

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF #	Manufacturer	Component
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Sulfate

13. DOSAGE FORM

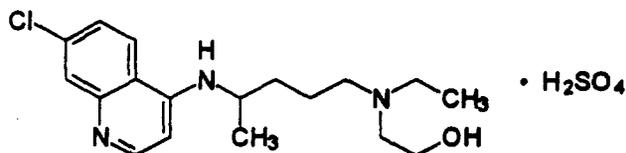
Tablet

14. POTENCY

200 mg

15. CHEMICAL NAME AND STRUCTURE

$C_{19}H_{26}ClN_3O \cdot H_2SO_4$. Ethanol, 2-[[4-(7-chloro-4-quinolinyl)amino]pentyl]-ethylamino-, (\pm)-, sulfate (1:1) (salt).



16. RECORDS AND REPORTS

None

17. COMMENTS

The application was found approvable.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

Kathy P. Woodland

DATE COMPLETED:

5/13/98

Page(s)

13

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev 2

5/13/98

1. CHEMISTRY REVIEW NO. 1

2. ANDA # 40-274

3. NAME AND ADDRESS OF APPLICANT

Mylan Pharmaceuticals Inc.
781 Chestnut Ridge Road
P.O. Box 4310
Morgantown, WV 26504-4310
(304) 599-2595

4. LEGAL BASIS FOR SUBMISSION

Plaquenil Sulfate (Sanofi Winthrop Pharmaceuticals)

Mylan certifies that to the best of their knowledge that there are no patents and the product is not covered by any exclusivity provisions.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Hydroxychloroquine Sulfate

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

N/A

9. AMENDMENTS AND OTHER DATES:

Amendment September 19, 1997

10. PHARMACOLOGICAL CATEGORY

Antimalarial, suppressant
(lupus erythematosus).

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF #	Manufacturer	Component
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13. DOSAGE FORM

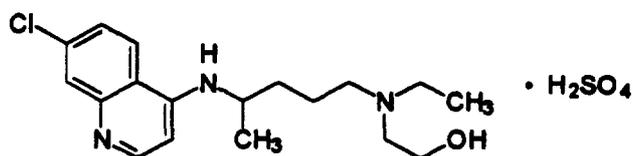
Tablet

14. POTENCY

200 mg

15. CHEMICAL NAME AND STRUCTURE

$C_{18}H_{26}ClN_3O \cdot H_2SO_4$. Ethanol, 2-[[4-(7-chloro-4-quinolinyl)amino]pentyl]-ethylamino-, (\pm)-, sulfate (1:1) (salt).



16. RECORDS AND REPORTS

None

17. COMMENTS

The application was found deficient.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is not approvable.

19. REVIEWER:

Kathy P. Woodland

DATE COMPLETED:

1/7/98

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releasable.

Chem Rev. 1