

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER      74976**

**CHEMISTRY REVIEW(S)**

1. CHEMISTRY REVIEW NO. 3

2. ANDA 74-976

3. NAME AND ADDRESS OF APPLICANT

Genpharm Inc.  
85 Advance Road  
Etobicoke, Ontario  
Canada M8Z 2S9

4. LEGAL BASIS FOR SUBMISSION

The applicant certifies, that to the best of its knowledge, U.S. Patent No. 4,199,574 will expire on April 22, 1997, and the product is not covered by any exclusivity provisions.

Innovator: Glaxo Wellcome - Zovirax<sup>®</sup>

5. SUPPLEMENT(s)  
N/A

6. PROPRIETARY NAME  
N/A

7. NONPROPRIETARY NAME  
Acyclovir

8. SUPPLEMENT(s) PROVIDE(s) FOR:  
N/A

9. AMENDMENTS AND OTHER DATES:

Firm: 9/27/96 - Original.  
1/16/97 - O/NC, Bio.  
1/22/97 - O/NC, Bio.  
2/5/97 - O/NC, Bio.  
6/2/97 - Response to 1st Bio. def. letter.  
9/8/97 - Response to phone memo, Bio. information.  
10/1/97 - Response to 1st def. letter (chem. & labeling).  
12/12/97 - Response to 2nd def. facsimile (chem. & labeling). Subject of this review.  
1/7/98 - Response to def. facsimile for 74-977 (labeling).  
2/20/98 - Response to phone memos. Subject of this review.

FDA: 12/4/96 - Acknowledgment.  
4/30/97 - 1st Bio. def. letter.  
5/20/97 - 1st def. letter (chem. & labeling).  
10/5/97 - Bio, review acceptable.  
10/10/97 - Bio. letter, no further questions.  
11/17/97 - 2nd def. facsimile (chem. & labeling).  
2/9/98 - Phone memo, regarding  
2/12/98 - Phone memo, clarification.

10. PHARMACOLOGICAL CATEGORY  
Antiviral

11. Rx or OTC  
R

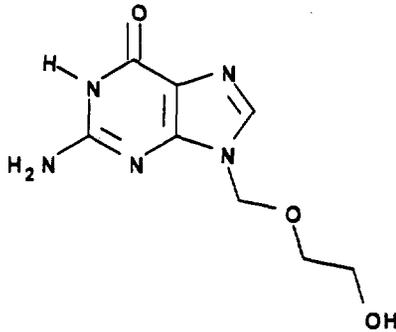
12. RELATED-IND/NDA/DMF (s)

13. DOSAGE FORM  
Tablet

14. POTENCIES  
400 mg & 800 mg

15. CHEMICAL NAME AND STRUCTURE

Acyclovir USP  
C<sub>8</sub>H<sub>11</sub>N<sub>5</sub>O<sub>3</sub>; M.W. = 225.21



9-[(2-Hydroxyethoxy)methyl]guanine. CAS [59277-89-3]

16. RECORDS AND REPORTS  
N/A

17. COMMENTS

a. Finished product method validation sent to St. Louis on 10/23/97.

DMF, EER, labeling, and Bio. acceptable.

18. CONCLUSIONS AND RECOMMENDATIONS  
Approval

19. REVIEWER:  
Norman Gregory

DATE COMPLETED:  
1/6/98; 2/24/98