

CENTER FOR DRUG EVALUATION AND RESEARCH

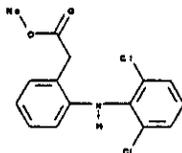
APPLICATION NUMBER: 74-986

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 6
2. ANDA # 74986
3. NAME AND ADDRESS OF APPLICANT
Martec Scientific Incorporated
Attention: Paul T. Sudhakar
1800 N. Topping Avenue
PO Box 33510
Kansas City, MO 64120-3510
4. LEGAL BASIS FOR SUBMISSION
Approved Product Voltaren® of Geigy Pharmaceuticals
5. SUPPLEMENT(s)
N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Diclofenac Sodium DR Tablets, USP
8. SUPPLEMENT PROVIDES FOR
N/A
9. AMENDMENTS AND OTHER DATES:
Original Submission as Two Separate Applications, #74986
(50mg tablet strength) & (75mg tablet strength);
Application Date 10/10/96.
Withdrawal of ANDA Date 12/01/96 (both 50mg & 75mg tablet
strengths combined into one ANDA #74986).
Major Amendment Date August 22, 1997.
Minor Amendment Date February 24, 1998
Major Amendment Date June 15, 1998
Minor Amendment Date November 27, 1998
Minor Amendment Date January 5, 1999 (This Review)
Tcon. Date February 8, 1999 (M. Anderson vs. Firm)
Telephone Amendment Date February 8, 1999 (This Review)
10. PHARMACOLOGICAL CATEGORY:
NSAID
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
Withdrawn. The two tablet strengths, 50mg & 75mg,
combined into one single ANDA #74986.

See Section 37 for DMF's
13. DOSAGE FORM
Enteric-coated Tablets
14. POTENCY
50 mg and 75 mg
15. CHEMICAL NAME AND STRUCTURE

Diclofenac Sodium
 $C_{14}H_{10}Cl_2NNaO_2$; M.W. = 318.13



Sodium [o-(2,6-dichloroanilino)phenyl]acetate. CAS [15307-79-6]

16. RECORDS AND REPORTS:

N/A

17. COMMENTS:

See individual review sections; comments from deficiency letter are followed by firm's response.

18. CONCLUSIONS AND RECOMMENDATIONS:**Approvable**19. REVIEWER:

U.S. Atwal

DATE COMPLETED:

January 8, 1999

Page(s) 12

Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

Chemistry