

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***  
**20-555/S-003/S-004**

**CHEMISTRY REVIEW(S)**

Folkendit

|                                                                                                                                                                                             |  |                                         |  |                                                                                                                     |                      |
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| CHEMISTRY REVIEW<br>#1                                                                                                                                                                      |  | 1. Organization:<br>HFD-180             |  | 2. NDA Number: JUN 10 1997<br>20-555                                                                                |                      |
| 3. Name & Address of Applicant:<br>Whitehall-Robins Healthcare<br>5 Giralda Farms<br>Madison, NJ 07940                                                                                      |  |                                         |  | 4. AF Number:                                                                                                       |                      |
|                                                                                                                                                                                             |  |                                         |  | 5. Supplement                                                                                                       |                      |
|                                                                                                                                                                                             |  |                                         |  | Number                                                                                                              | Date                 |
| 6. Drug Name:<br>Axid AR                                                                                                                                                                    |  | 7. Nonproprietary:<br>nizatidine        |  | SE1-003<br>SE2-004                                                                                                  | 12/16/96<br>03/31/97 |
| 8. Supplements Provide For additional<br>nonprescription indications.                                                                                                                       |  |                                         |  | 9. Amendments & Reports:<br>BC 04/16/97                                                                             |                      |
| 10. Category:                                                                                                                                                                               |  | 11. Dispensed:<br>OTC                   |  | 12. Related Docs:<br><div style="border: 1px solid black; height: 40px; width: 100%;"></div><br>NDA 19-508 capsules |                      |
| 13. Dosage Form:<br>F/C tablets                                                                                                                                                             |  | 14. Potency:<br>75 mg                   |  |                                                                                                                     |                      |
| 15. Chemical Name & Structure: USP 23                                                                                                                                                       |  |                                         |  | 16. Records & Reports:                                                                                              |                      |
|                                                                                                                                                                                             |  |                                         |  | Current: Yes ___ No ___                                                                                             |                      |
|                                                                                                                                                                                             |  |                                         |  | Reviewed: Yes ___ No ___                                                                                            |                      |
| 17. Comments: See Review Notes<br><br>c/c: NDA 20-555<br>HFD-180/Div File<br>HFD-181/CSO/MFolkendt<br>HFD-180/LTalarico<br>HFD-180/MAdams<br>R/D init: EDuffy/6-26-97<br>MA/dob F/T 6-30-97 |  |                                         |  |                                                                                                                     |                      |
| 18. Conclusions and Recommendations:<br>Supplement is APPROVABLE with respect to the EMC information.                                                                                       |  |                                         |  |                                                                                                                     |                      |
| 19. Reviewer                                                                                                                                                                                |  |                                         |  |                                                                                                                     |                      |
| Name:<br>MIKE ADAMS                                                                                                                                                                         |  | Signature: <i>4/30/97</i><br><i>/S/</i> |  | Date Completed:<br>06/30/97                                                                                         |                      |
| Distribution //Original Jacket //Reviewer //Division File                                                                                                                                   |  |                                         |  |                                                                                                                     |                      |

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| CHEMISTRY REVIEW<br>#2                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | 1. Organization:<br>HFD-180              |  | 2. NDA Number: DEC 17 1997<br>20-555       |          |
| 3. Name & Address of Applicant:<br>Whitehall-Robins Healthcare<br>Five Giralda Farms<br>Madison, NJ 07940-0871                                                                                                                                                                                                                                                                                                                                                                           |  |                                          |  | 4. AF Number:                              |          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |                                          |  | 5. Supplement                              |          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |                                          |  | Number                                     | Date     |
| 6. Drug Name:<br>Arid® AR                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | 7. Nonproprietary:<br>nizatidine tablets |  | SEI-003                                    | 12/16/96 |
| 8. Supplement Provides For: an additional indication                                                                                                                                                                                                                                                                                                                                                                                                                                     |  |                                          |  | 9. Amendments & Reports:<br>amend 12/12/97 |          |
| 10. Category:<br>stomach acid relief                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | 11. Dispensed:<br>OTC                    |  | 12. Related Docs:                          |          |
| 13. Dosage Form:<br>F/C tablet                                                                                                                                                                                                                                                                                                                                                                                                                                                           |  | 14. Potency:<br>75 mg                    |  |                                            |          |
| 15. Chemical Name & Structure: USP 23                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |                                          |  | 16. Records & Reports:                     |          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |                                          |  | Current: Yes ___ No ___                    |          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  |                                          |  | Reviewed: Yes ___ No ___                   |          |
| 17. Comments: See Review Notes<br>c/c:<br>NDA 20-555<br>HFD-180/Div File<br>HFD-181/CSO/M.Folkendt<br>HFD-180/L.Talarico/Div Dir<br>HFD-820/M.Adams<br>HFD-820/J.Gibbs/Dir DNDC II<br>HFD-820/S.Koepke/DepDir DNDC II<br>R/D init E.Duffy/12- -97<br>typist: WP: <span style="border: 1px solid black; display: inline-block; width: 150px; height: 1.2em; vertical-align: middle;"></span> <div style="position: absolute; left: 520px; top: 550px; font-size: 2em;">/S/ 12/17/97</div> |  |                                          |  |                                            |          |
| 18. Conclusions and Recommendations:<br>The submitted CMC information is acceptable for APPROVAL (AP) of the proposed supplemental changes.                                                                                                                                                                                                                                                                                                                                              |  |                                          |  |                                            |          |
| 19. Reviewer                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |  |                                          |  |                                            |          |
| Name:<br>MIKE ADAMS                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  | Signature: 12/16/97<br>/S/               |  | Date Completed:<br>12/16/97                |          |
| Distribution //Original Jacket //Reviewer //Division File                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                          |  |                                            |          |

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| CHEMISTRY REVIEW<br>#2                                                                                                                                                                                                                                                                                                |  | 1. Organization:<br>HFD-180              |  | 2. NDA Number: JAN 13 1998<br>20-555          |          |
| 3. Name & Address of Applicant:<br>Whitehall-Robins Healthcare<br>Five Giralda Farms<br>Madison, NJ 07940-0871                                                                                                                                                                                                        |  |                                          |  | 4. AF Number:                                 |          |
|                                                                                                                                                                                                                                                                                                                       |  |                                          |  | 5. Supplement                                 |          |
|                                                                                                                                                                                                                                                                                                                       |  |                                          |  | Number                                        | Date     |
| 6. Drug Name:<br>AxiD <sup>®</sup> AR                                                                                                                                                                                                                                                                                 |  | 7. Nonproprietary:<br>nizatidine tablets |  | SE2-004                                       | 03/31/97 |
| 8. Supplement Provides For: an additional indication                                                                                                                                                                                                                                                                  |  |                                          |  | 9. Amendments & Reports:<br>BC amend 12/30/97 |          |
| 10. Category:<br>stomach acid relief                                                                                                                                                                                                                                                                                  |  | 11. Dispensed:<br>OTC                    |  | 12. Related Docs:                             |          |
| 13. Dosage Form:<br>F/C tablet                                                                                                                                                                                                                                                                                        |  | 14. Potency:<br>75 mg                    |  |                                               |          |
| 15. Chemical Name & Structure: USP 23                                                                                                                                                                                                                                                                                 |  |                                          |  | 16. Records & Reports:                        |          |
|                                                                                                                                                                                                                                                                                                                       |  |                                          |  | Current: Yes ___ No ___                       |          |
|                                                                                                                                                                                                                                                                                                                       |  |                                          |  | Reviewed: Yes ___ No ___                      |          |
| 17. Comments: See Review Notes<br>c/c:<br>NDA 20-555<br>HFD-180/Div File<br>HFD-181/CSO/M.Folkendt<br>HFD-180/L.Talarico/Div Dir<br>HFD-820/M.Adams<br><del>HFD-820/J.Gibbs/Dir DNDC II</del> 1/13/98<br><del>HFD-820/S.Koopke/DepDir DNDC II</del> /S/ 1/13/98<br>R/D init E.Duffy/01-12-98<br>MA/dob F/T 1-13-98/WP |  |                                          |  |                                               |          |
| 18. Conclusions and Recommendations:<br>The submitted CMC information is acceptable for APPROVAL (AP) of the proposed supplemental changes.                                                                                                                                                                           |  |                                          |  |                                               |          |
| 19. Reviewer                                                                                                                                                                                                                                                                                                          |  |                                          |  |                                               |          |
| Name:<br>MIKE ADAMS                                                                                                                                                                                                                                                                                                   |  | Signature:<br>/S/ 1-13-98                |  | Date Completed:<br>01/09/98                   |          |
| Distribution //Original Jacket //Reviewer //Division File                                                                                                                                                                                                                                                             |  |                                          |  |                                               |          |