1. CHEMISTRY REVIEW NO. 3

2. ANDA # 75-105

3. NAME AND ADDRESS OF APPLICANT
   Alphapharm Pty., Ltd.
   Attention: Anita M. Goodman, M.D.
   U.S. Agent for: Alphapharm Pty., Ltd.
   9 West 57th Street, Suite 3825
   New York, NY 10019-2701

4. LEGAL BASIS FOR SUBMISSION
   Approved Product Lozol® Tablets of Rhone-Poulenc Rorer.

5. SUPPLEMENT(s) 6. PROPRIETARY NAME
   N/A  N/A

7. NONPROPRIETARY NAME 8. SUPPLEMENT(s) PROVIDE(s) FOR:
   Indapamide, USP  N/A

9. AMENDMENTS AND OTHER DATES:
   Application Submission Date March 20, 1997
   Major Amendment Date December 11, 1997
   Amendment Date May 29, 1998 (This Review)

10. PHARMACOLOGICAL CATEGORY
    For the treatment of Hypertension, and for the treatment of salt
        and fluid retention associated with Congestive Heart Failure.

11. Rx or OTC
    Rx

12. RELATED IND/NDA/DMF(s)
    See DMF Section (37)

13. DOSAGE FORM 14. POTENCY
    Tablet  1.25 mg & 2.5 mg

15. CHEMICAL NAME AND STRUCTURE

   Indapamide USP
   \text{C}_10\text{H}_{16}\text{ClN}_3\text{O}_3\text{S}; M.W. = 365.83

   ![Chemical Structure](image)

   4-Chloro-N-(2-methyl-1-indolinyl)-3-sulfamoylbenzamide.
   CAS [26807-65-8]
16. RECORDS AND REPORTS N/A

17. COMMENTS
   See Review; comments from deficiency letter are followed by firm's response.

18. CONCLUSIONS AND RECOMMENDATIONS
   Approvable

19. REVIEWER: DATE COMPLETED:
    U.S. Atwal June 16, 1998
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Contain Trade Secret, Commercial/Confidential Information and are not releasable.

Chem Rev 3

6/16/98