

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 19532**

**CHEMISTRY REVIEW(S)**

DIVISION OF CARDIO-RENAL DRUG PRODUCTS  
REVIEW AND EVALUATION OF MANUFACTURING AND CONTROLS DATA  
CHEMIST'S REVIEW

Date Completed: August 24, 1987

A. 1. NDA 19-532

Sponsor: Pennwalt Corporation  
Pharmaceutical Division  
755 Jefferson Rd.  
Rochester, NY 14623

(AF#: [REDACTED])

2. Product Name (s): MICROX Tablets

Proprietary: MICROX

Nonproprietary: Metolazone

USAN: Metolazone

Compendium: none

Code Name and/or Number: [REDACTED]

CAS No. 17560-51-9

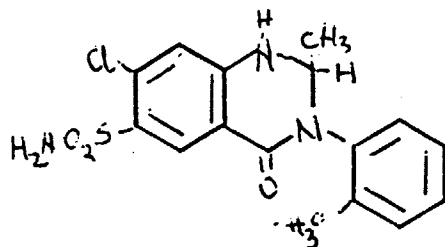
3. Dosage Form and Route of Administration:

Compressed tablets for oral administration.

4. Pharmacological Category and/or Principal Indications:

Antihypertensive agent.

5. Structural Formula and Chemical Name:



Chemical name:

7-Chloro-1,2,3,4-tetrahydro-2-methyl-3-(3-methylphenyl)-4-oxo-6-quinazoline-sulfonamide.

## Alternative names:

7-Chloro-1,2,3,4-tetrahydro-2-methyl-4-oxo-3-o-tolyl-6-quinazolinesulfonamide.

2-Methyl-3-o-tolyl-6-sulfamyl-7-chloro-1,2,3,4-tetrahydro-4-quinazoline.

Empirical Formula:  $C_{16}H_{16}ClN_3O_3S$

Molecular Weight: 365.84

- B. 1. Initial Submission: October 4, 1985  
Received CDB                      October 8, 1985  
Assigned:                              October 11, 1985
2. Amendments:  
November 19, 1985  
May 15, 1986  
September 12, 1986  
September 25, 1986  
March 27, 1987 - revised package circular.  
May 29, 1987 - revised package circular.  
  
August 17, 1987 - dissolution data on ~~XXXXXXXXXX~~.
3. Supporting INDs, NDAs, MFs and Letters of Authorization:

4. Related Documents (INDs, NDAs, etc.):

None.

- C. Remarks:

D. Conclusions and/or Recommendations:

All questions raised in the manufacturing and controls reviews were answered satisfactorily.

Chemist's part of SBA has been written.

EIAR - little or no impact on the environment.

Methods validation - satisfactory. Problems encountered during validation were solved.

EI - acceptable, November 7, 1985.

/S/

Danute G. Cunningham

cc:

Orig.

HEN-110

HFN-110/CSO

HFN-110/DGCunningham

Doc. # 0452D

*11-10-85*