

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

19-386

Chemistry Review(s)

DEC 2 1985

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

Chemist's Review #3

Date Completed: Dec. 5, 1985

A. 1. NDA #: 19-386

SPONSOR: American Critical Care
American Hospital Supply Corporation
McGaw Park, IL 60085

AF #: [REDACTED]

2. Product Name(s):

Proprietary - BREVIBLOC INJECTION

Nonproprietary - Esmolol Hydrochloride

USAN - Official, 1983

Compendium - None

Code Name and/or Number - [REDACTED]

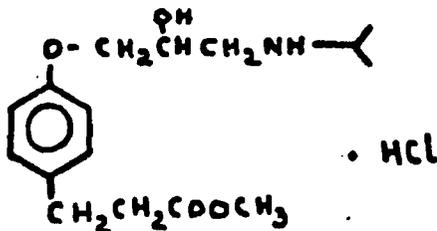
3. Dosage Form and Route of Administration:

Sterile Liquid - 1g/10ml and 2.5g/10ml. Intravenous infusion after dilution. Rx only.

4. Dosage Form and Route of Administration:

Anti-adrenergic (B-receptor)

5. Structural Formula and chemical Name:



Methyl 3-[4-[2-hydroxy-3-(isopropylamino)propoxy]phenyl] propionate hydrochloride

B. 1. Initial Submission: Jan. 8, 1985.

C. Remarks:

At the request of the agency, the firm changed the chemical names of the impurities [REDACTED]. The new names are suggested by the chemical abstracts service and they are satisfactory.

The firm also agreed to revise the carton labels to emphasize the statement "Not for direct IV injection." Depending on the final layout, this phrase will appear either in a contrasting color, or in bold type letters.

D. Conclusions and/or Recommendations:

The application is approvable from the standpoint of manufacturing and controls. All the outstanding matters are resolved.

B. Rao Vishnuvajjala 12/31/85

B. Rao Vishnuvajjala, Ph.D.
Chemist

cc: Orig. NDA
HFN/110
HFN/110/CSD
HFN/110/RVishnuvajjala/12/10/85
R/D Init.: BWolters/12/9/85
keg/12/23/85/2577s