

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-909

ADMINISTRATIVE DOCUMENTS

APPROVAL SUMMARY

ANDA: 75-909

DRUG PRODUCT: Enalapril Maleate/Hydrochlorothiazide Tablets USP

FIRM: Dr. Reddy's Laboratories Limited

DOSAGE FORM: Oral Tablets

STRENGTH: 5 mg/12.5 mg and 10 mg/25 mg

cGMP STATEMENT/EER UPDATE STATUS: Acceptable (EGASM, 8/11/00)

BIO STUDY: Acceptable (P. Nwakama, 9/29/00)

The recommended dissolution specifications and conditions are as follows:

900 mL of Water, at 37 °C using USP Apparatus 2 (Paddle) at 50 rpm.

Enalapril Maleate -) in 30 minutes
 Hydrochlorothiazide - in 30 minutes

VALIDATION: N/A

STABILITY: The container/closure system used for the stability study (100-unit and 1000-unit packaging configurations) is equivalent to the system proposed for commercial use. All reported data are within specifications as listed. A 24-month expiration date is proposed.

Stability tests and specifications are as follows:

	Specifications
Physical Description	
Dissolution	
Assay	
Related Compounds	
LOD	

LABELING: Acceptable in Draft (J. Barlow, 9/27/01)

STERILIZATION VALIDATION: (IF APPLICABLE): N/A

SIZE OF BIO Batch:

Reddy-Cheminor manufactured two ANDA batches, one for each strength. The batch size and lot numbers are as follows:

<u>Strength</u>	<u>Lot Number</u>	<u>Batch size</u>	<u>Purpose</u>
5 mg/12.5 mg	E001A		stability
10 mg/25 mg	E001B		bioequivalence/stability

SIZE OF STABILITY BATCHES: See above

PROPOSED PRODUCTION BATCHES:

The batch sizes for the proposed production batches are as follows:

<u>Strength</u>	<u>Proposed Production Batch size</u>
5 mg/12.5 mg	
10 mg/25 mg	

Review Chemist: Andre Raw
Andre Raw, Ph.D.

DATE: 10/1/01

Team Leader: Albert Mueller
Albert Mueller, Ph.D.

DATE: 10/1/01

V:

**REVIEW OF PROFESSIONAL LABELING
DIVISION OF LABELING AND PROGRAM SUPPORT
LABELING REVIEW BRANCH**

ANDA Number:	75-909
Date of Submission:	June 16, 2000
Applicant's Name:	Cheminor Drugs Limited (manufactured for Par Pharmaceuticals)
Established Name:	Enalapril Maleate and Hydrochlorothiazide Tablets USP, 5 mg/12.5 mg & 10 mg/25 mg.

Labeling Deficiencies:

1. **CONTAINER** – Bottles of 100 and 1000 tablets
Please assure that the established name and expression of strength are the **most prominent print** on the label.

2. **PACKAGE INSERT**
 - a. **General Comments**
Please note that USAN names are common nouns and should be treated as such in the text of labeling (i.e., lower case). Upper case may be used when the USAN name stands alone as on labels or in the title of the package insert .

 - b. **Title:**
We encourage you to include "USP" in the established name of your drug product in this section.

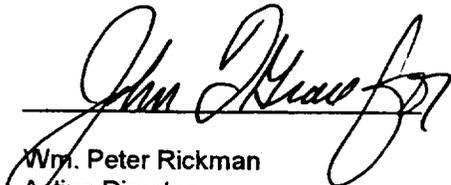
 - c. **Description**
Third paragraph, first sentence –

...with a molecular weight of 492.53.[replace "with" with "weight" and replace "492.52" with "492.53"]

Please revise your labels and labeling, as instructed above, and submit in final print, or draft if you prefer.

Prior to approval, it may be necessary to further revise your labeling subsequent to approved changes for the reference listed drug. We suggest that you routinely monitor the following website for any approved changes-http://www.fda.gov/cder/ogd/rld/labeling_review_branch.html

To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.


Wm. Peter Rickman
Acting Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research