

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-140

ADMINISTRATIVE DOCUMENTS

ANDA APPROVAL SUMMARY

ANDA: 75-140 DRUG PRODUCT: Terazosin Hydrochloride

Applicant: Mylan Pharmaceuticals Inc.

DOSAGE FORM: Capsules STRENGTH: 1 mg, 2 mg, 5 mg, 10 mg

CGMP STATEMENT/EIR UPDATE STATUS: EER acceptable 12/20/99.

BIO Bio review was completed and signed off by Dale P. Conner on 03/18/98. A bio acceptance letter was faxed to Mylan on 06/04/98. The current specifications recommended by DOB is as follows:

Medium: water, 900 mL
Apparatus: USP 23, paddle
Speed: 50 rpm
Dissolution Specification:

VALIDATION: Satisfactory

Mylan has satisfactorily responded to the District Laboratory's comments in the 02/03/00 MINOR amendment)

STABILITY:

Three months accelerated stability data were submitted for the four new executed batches (see CR #2, and CR #3). Containers used in the studies are identical to those in the container section.

The current test parameters and specs are as follows:

LABELING: Acceptable per labeling review dated 07/27/98(J. Barlow).

STERILIZATION VALIDATION (IF APPLICABLE): N/A

SIZE OF BIO BATCH capsules (lot #2C012N, 5 mg strength)

Bulk Drug Substance Source:

SIZE OF STABILITY BATCHES: Same as the biobatch (capsules).

PROPOSED PRODUCTION BATCH: Manufacturing process is same as the biobatch. Batch sizes for intended maximum production are capsules.

REVIEWER: S. Liu, Ph.D.

DATE COMPLETED: 02/10/2000

Team Leader: Devinder Gill, Ph.D.

ELECTRONIC MAIL MESSAGE

Date: 04-Jun-1998 02:21pm EDT
From: Shing Hou Liu
LIUS
Dept: HFD-623 MPN2 204
Tel No: 301-827-5848 FAX 301-594-0180

TO: Joseph Buccine (BUCCINE)
CC: Vilayat Sayeed (SAYEEDV)
Subject: ANDA 75-140 Mylan-Terazosin HCl (Dissolution Specs)

Joe,

Thank you for faxing the bio acceptance letter (signed by Dale Conner on 03/18/98) to Mylan. The bio letter contains the current dissolution specification recommended by FDA:

Medium: Water, 900 mL
Apparatus: USP 23, paddle
Speed: 50 rpm
Dissolution specification: NLT 80% in 60 min.

Please be advised that Mylan has provided dissolution data for finished drug product and three months accelerated stability studies of the executed ANDA batches for all four strengths (1 mg, 2 mg, 5 mg, and 10 mg). Their data are based on the following dissolution specs:

Medium: Water, 900 mL
Apparatus: USP 23, paddle
Speed: 50 rpm
Dissolution specification:

If Mylan calls you after they receive the bio fax letter, please tell them that the ANDA is under review, and any issue related to dissolution will be conveyed to them when the chemistry review is completed. Thanks.

Shing