CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75465

MEDICAL REVIEW

ANDA APPROVAL SUMMARY

ANDA: 75-465

DRUG PRODUCT: Fluoxetine Capsules USP, 10 mg, 20 mg, and 40 mg.

FIRM: Reddy-Cheminor, Inc.

DOSAGE FORM: Capsules

STRENGTHS: 10 mg, 20 mg, and 40 mg.

CGMP STATEMENT/EIR UPDATE STATUS:

Manufacturer-Finished Dosage Form :

The drug product will be manufactured, processed, controlled, packaged, and labeled at Cheminor Drugs Limited:

Cheminor Drugs Limited
Via IDA Bollaram
Bachepalli- 502 325
India
(OK on 8-1-99).

nufacturer-Active Ingredients:

The manufacturer of the drug substance, Fluoxetine Hydrochloride USP, is:

Dr. Reddy's Laboratories LTD.
Plot No. 137 &138,
Sri Venkateswara Co-operative Industrial Estate,
Bollaram, Narsapur Tq.
Medak Dt.
Andhra Pradesh, INDIA
DMF
(OK on 8-1-99).

Contract Laboratories:

None except analysis of container/closure system

This outside Laboratory will perform the container testing for the container/closure systems.

2. Dr. Reddy's Research Foundation

Bollaram Road, Miyapur
Hyderabad 500138
Andhra Pradesh, India

This outside Laboratory performed the Differential Scanning Colorimetry (Thermal Analysis) testing for the container/closure systems.

BIO STUDY:

Satisfactory per K Dhariwal reviewed on 11-8-2000 for 10 mg, 20 mg and 40 mg.

10 mg strength: in vitro dissolution testing
I. Executed batch #001A, USA
II. Executed batch #001B, Canada

20 mg strength: Bio-batch study and fasting and non-fasting conditions
I. Executed batch #001[Lot I], USA
II. Executed batch #001[Lot II], Canada

40 mg strength: in vitro dissolution testing under fasting
Executed batch ##E001

VALIDATION -(DESCRIPTION OF DOSAGE FORM SAME AS FIRM'S):

Compendial drug substance and drug product.
This product is now the subject of a USP monograph so no FDA sample testing is required.

STABILITY - ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION?:

Stability protocol: Satisfactory

Expiration dating:

2 years expiration date with 1, 2 and 3 month accelerated stability data (40°C/75% R.H.) and 3 month room temperature stability data (25°C±2°C/60%±5%) on batch No.:001A for 30's and 100's (85 cc HDPE bottle) capsules package sizes for 10 mg, and on batch No.:001 (Lot-1) for 30's, 100's (85 cc HDPE bottle) and 1000's (950 cc) capsules package sizes for 20 mg, and on batch No.:E001 for 30's, 500's and unit dose blister (10's - only 3 months accelerated) capsules package sizes for 40 mg.

LABELING:

Satisfactory per A. Vezza reviewed on 6-8-2001 for TA letter only.

STERILIZATION VALIDATION (IF APPLICABLE):

NA

SIZE OF BIO BATCH (FIRM'S SOURCE OF NDS OK?):

10 mg strength:
I. capsules (executed batch #001A, USA)
II. capsules (executed batch #001B, Canada)

20 mg strength:
I. capsules (executed batch #001[Lot I], USA)
II. capsules (executed batch #001[Lot II], Canada)

40 mg strength:
capsules (executed batch ##E001)

DMF was reviewed and found satisfactory by L. Tang on 2-24-2000.

SIZE OF STABILITY BATCHES - (IF DIFFERENT FROM BIO BATCH, WERE THEY MANUFACTURED VIA THE SAME PROCESS?):

The stability batch size:

10 mg strength batch # batch #001A: cap batch size

20 mg strength batch #batch #001[Lot I](Bio-batch for fasting and non-fasting conditions): cap batch size

40 mg strength batch # ##E001 (in-vitro for fasting conditions):
cap batch size

PROPOSED PRODUCTION BATCH - MANUFACTURING PROCESS THE SAME AS BIO/STABILITY?:

The proposed production batch (blank batch):

10 mg strength capsules

20 mg strength Capsules

40 mg strength capsules

The proposed production batches have the same manufacturing process as the test batches or Bio-batches (see above). Scale-up meets OGD PPG 22-90.

CHEMIST: Lucia C. Tang DATE: 6-12-01

SUPERVISOR: Ubrani Venkataram DATE: 6-14-01

/S/ 6/20/2001.

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