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RESEARCH**

APPLICATION NUMBER:

76-200/S-001

CHEMISTRY REVIEW(S)

ANDA 76-200/S-001

NAME AND ADDRESS OF APPLICANT:

Corepharma LLC
Attention: Mukteeshwar Gande, M.S., R.Ph.
215 Wood Avenue
Middlesex, NJ 08846

PURPOSE OF AMENDMENT/SUPPLEMENT

The CBE-0 supplement provides for:

S-001 confirmation of FDA suggested "interim" dissolution specification

DATE(S) OF SUBMISSION(S)

April 18, 2002

PHARMACOLOGICAL CATEGORY

Analgesic

TRADE NAME

N/A

NONPROPRIETARY NAME

Acetaminophen
Extended Release
Tablets 650 mg

DOSAGE FORM

Tablet, oral

POTENCY

650 mg

RX OR OTC

Rx

SAMPLES

N/A

RELATED IND/NDA/DMF

N/A

STERILIZATION

N/A

LABELING

N/A

BIOEQUIVALENCY STATUS

Acceptable dissolution data confirming the interim specification for dissolution is provided for lots #CPA223, #CPB213, and #CPB214.

Method: 900 mL of Simulated Gastric Fluid without enzyme, pH 1.2 USP apparatus II (paddle) at 50 rpm.

Specification:

Time (min.)	Mean (% of claim)
15	_____
60	_____
180	NLT _____

ESTABLISHMENT INSPECTION

N/A

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

Updated specifications and test method QCM-117 (Dissolution assay for initial and stability samples) modified to finalize the dissolution specification are provided.

PACKAGING

N/A

STABILITY

See CCMC section above.

REMARKS AND CONCLUSION

Recommend approval.

RECALLS

N/A

Reviewer

M. Piñeiro-Sánchez, Ph.D.

Date Completed

August 7, 2002

ORDER OF REVIEW:

The application submission(s) covered by this review was taken in the date order of receipt Yes X

No _____

If no, explain reason(s) below.

**APPEARS THIS WAY
ON ORIGINAL**