

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-224

BIOEQUIVALENCE

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA/AADA # 75-224

SPONSOR :Taro Pharmaceuticals

DRUG & DOSAGE FORM :Clobetasol Propionate Topical Solution

STRENGTH (s) : 0.05%

TYPE OF STUDY: Waiver

STUDY SITE: CLINICAL : NA

ANALYTICAL :

STUDY SUMMARY : NA waiver

Parameter test ref ratio 90% CI (log).

Cmax(ng/ml)

AUC(0-T) ngxhr/ml

AUC(0-Inf)ngxhr/ml

Tmax hr

Half-life hr

DISSOLUTION :NA

Conditions:

PRIMARY REVIEWER : Andre Jackson

BRANCH : I

INITIAL : af

DATE : 3/2/98

BRANCH CHIEF :Y.C. Huang

BRANCH :I

INITIAL : YCH

DATE : 3/3/98

DIRECTOR

DIVISION OF BIOEQUIVALENCE: D.P. Conner

INITIAL : DP

DATE : 3/3/98

DIRECTOR

OFFICE OF GENERIC DRUGS

INITIAL : _____

DATE : _____