

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER** 40-323

**ADMINISTRATIVE DOCUMENTS**

OFFICE OF GENERIC DRUGS  
ABBREVIATED NEW DRUG APPLICATION

ANDA APPROVAL SUMMARY

ANDA: 40-323

DRUG PRODUCT: Prednisolone Syrup USP

FIRM: UDL Laboratories, Inc.

DOSAGE FORM: Syrup

STRENGTH: 15 mg/5mL

CGMP STATEMENT/EIR UPDATE STATUS:

An establishment Evaluation Report has been submitted (7-1-98). Facility inspection for UDL has been assigned. Recommendation is currently pending. *Acceptable 5/11/99. aw.*

BIO STUDY:

UDL has requested a waiver from the requirement from performing an in-vivo bioequivalence study. Request for a waiver has been granted (M. Gokhale, 9-30-98).

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

Both drug substance and final drug product are USP compendial materials. Analytical methods are either USP methods or modified USP methods. All modified analytical methods have been validated.

STABILITY -

(ARE CONTAINERS USED IN STUDY IDENTICAL TO THOSE IN CONTAINER SECTION?):

The stability batch is identical to the bio batch.

LABELING:

All labeling issues have been resolved (J. Barlow, 12-29-98). Twelve copies of final printed label and insert have been attached to the application.

STERILIZATION VALIDATION (IF APPLICABLE):

The final drug product is monitored for sterility by USP sterility testing on release and at appropriate stability stations.

SIZE OF BIO BATCH - (FIRM'S SOURCE OF NDS O.K.):

The executed batch was \_\_\_\_\_ Liters in size. Approximately 94% of the executed batch was packaged in the proposed container/closure systems.

The Drug Master File \_\_\_\_\_ for the NDS is currently acceptable by review.

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

The stability batch is identical to the bio batch.

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

The proposed production batch will be produced in a similar manner as the bio batch. The executed batch was \_\_\_\_\_ Liters in size. Approximately 86% of the executed batch was packaged in the proposed container/closure systems. Master Batch Records for the scale-up batch size is \_\_\_\_\_ Liters (page 289).

CHEMIST: A.J. Mueller, Ph.D. *1/S/ 3-29-99* . DATE: March 29, 1999

SUPERVISOR: V.A. Sayeed, Ph.D. DATE: *1/S/ 3/31/99.*