

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 40-323

CHEMISTRY REVIEW(S)

OFFICE OF GENERIC DRUGS
ABBREVIATED NEW DRUG APPLICATION
CHEMISTRY, MANUFACTURING AND CONTROLS REVIEW

1. CHEMISTRY REVIEW NO. 3 (three)

2. ANDA # 40-323

3. NAME AND ADDRESS OF APPLICANT

UDL Laboratories, Inc.
Attention: Dina Kostakis
7265 Ulmerton Road
Largo, FL 33771

4. LEGAL BASIS FOR SUBMISSION

Prelone Syrup (Prednisolone Syrup, 15 mg/5mL);
ANDA 89-081, Muro Pharmaceuticals

5. SUPPLEMENT(s)

Not applicable

6. PROPRIETARY NAME

None

7. NONPROPRIETARY NAME

Prednisolone Syrup USP, 15 mg/5mL

8. SUPPLEMENT(s) PROVIDE(s) FOR:

Not applicable

9. AMENDMENTS AND OTHER DATES:

6-30-98 Date of Application
12-9-98 Date of Amendment

10. PHARMACOLOGICAL CATEGORY

Glucocorticoid

11. Rx or OTC R

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM

Syrup

14. POTENCY

15 mg/5mL

15. CHEMICAL NAME AND STRUCTURE

Generic name: Prednisolone

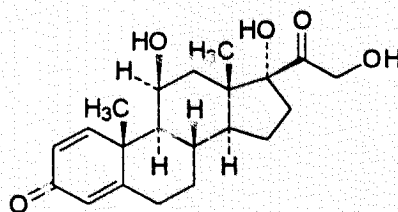
Chemical name: Pregna-1,4-diene-3,20-dione, 11,17,21-trihydroxy-,
(11 β) -Formula: C₂₁H₂₈O₅

Molecular weight: 360.45

CAS registry number(s): 50-24-8

Pharmacologic and/or therapeutic category: Glucocorticoid

Chemical structure:

16. RECORDS AND REPORTS

None

17. COMMENTS

The EER remains pending, otherwise this application is approvable.

18. CONCLUSIONS AND RECOMMENDATIONS

This application is approvable, pending EER.

19. REVIEWER:DATE COMPLETED:

A.J. Mueller, Ph.D.

March 29, 1999

AJ Mueller
4-1-2-99

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