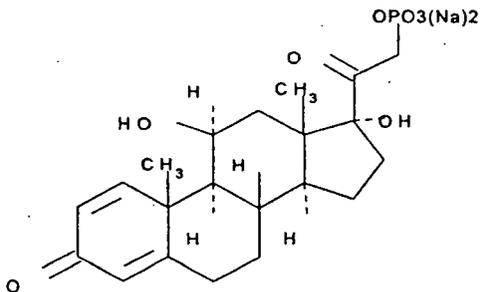


**CENTER FOR DRUG EVALUATION AND
RESEARCH
75-117**

APPLICATION NUMBER:

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 5
2. ANDA 75-117 (20.2 mg/5 mL; equivalent to 15 mg base/5 mL)
3. NAME AND ADDRESS OF APPLICANT
Ascent Pediatrics
Attention: William E. Brochu
187 Ballardvale Street, Suite B125
Wilmington, MA 01887
4. LEGAL BASIS FOR SUBMISSION
Pediapred® Oral Solution, NDA 19-157, EQ 5 mg base/5 mL, Medeva, Inc. Patent 4,448,774 expire on 05/21/2001, no exclusivity. Ascent is filing under paragraph IV (i.e., the firm claims its application does not violate Medeva's patent).
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME Orapred (TM) Solution
7. NONPROPRIETARY NAME Prednisolone Sodium Phosphate Oral Solution
8. SUPPLEMENT(s) PROVIDE(s) FOR N/A
9. AMENDMENTS AND OTHER DATES
04-21-1997 Original submission
07-14-2000 Response to minor deficiency letter of 5/1/00
09-21-2000 Fax amendment in relation to deficiency letter of 5/1/00
09-29-2000 MV commitment
10-23-2000 Information on flavoring
10. PHARMACOLOGICAL CATEGORY Glucocorticoid
11. Rx or OTC Rx
12. RELATED IND/NDA/DMF(s) See DMF checklist.
13. DOSAGE FORM Solution (Oral)
14. POTENCY 20.2 mg/5 mL (EQ to 15 mg base/5 mL)
15. CHEMICAL NAME AND STRUCTURE
11 β ,17,21-Trihydroxypregna-1,4 diene-3,20-dione 21-(disodium phosphate) M.W. = 484.40
C₂₁H₂₇Na₂O₈P [125-02-0]



16. RECORDS AND REPORTS N/A

17. COMMENTS None

18. CONCLUSIONS AND RECOMMENDATIONS Approvable

19. <u>REVIEWER:</u> Neeru B. Takiar	<u>DATE COMPLETED:</u>	09/18/00
Endorsed by D. Gill, Ph.D	Revised:	10/05/00
	Revised:	11/01/00

Note: Ascent submitted a fax amendment clarifying the correct specification for total related substances regarding the drug substance specifications, dated 9/21/00.

Ascent submitted a fax amendment providing the additional information regarding the flavor used in the subject ANDA, dated 10/23/00.

Page(s)

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Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

Chem Rev 5

9/18/00