CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 5970/S30

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW
(If necessary, continue any item on 8" x 10½" paper. Key continuation to item by number.)

1. ORGANIZATION	2. NDA NUMBER
FDA/HFN-160	5970

3. NAME AND ADDRESS OF APPLICANT *(City and State)*
Elkins - Sinn Inc.
Cherry Hill, New Jersey 08034

4. AF NUMBER

5. SUPPLEMENT (S)

NUMBER(S)	DATE(S)
S-030CS	8/22/86
S-030BL	8/25/86

6. NAME OF DRUG	7. NONPROPRIETARY NAME
Sotradecol Injection	Sodium Tetradecyl Sulfate Injection

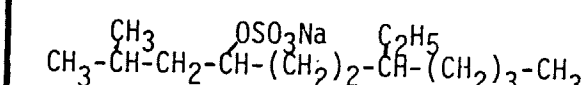
8. SUPPLEMENT(S) PROVIDES FOR:
changing the pH specification for Sotradecol gel (purified raw material) from

9. AMENDMENTS AND OTHER *(Reports, etc.)* **DATES**

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF(S)
Sclerosing Agent	☒ RX ☐ OTC	

13. DOSAGE FORM (S)	14. POTENCY (Iso)
Injection (intravenously)	1% and 3%

15. CHEMICAL NAME AND STRUCTURE



7-Ethyl-2-methyl-4-hendecanol sulfate sodium salt.

16. RECORDS AND REPORTS
CURRENT ☐ YES ☐ NO
REVIEWED ☐ YES ☐ NO

17. COMMENTS
The pH specification of the concentrate (i.e., Sotradecol gel NLT 40%) solution is
The sotradecol gel is diluted to 7% (pH = ?)
which in turn is diluted to 1% and 3% final concentration
The pH specification of the dilute solutions is

18. CONCLUSIONS AND RECOMMENDATIONS
NA letter is recommended. The deficiencies are outlined in the attached draft letter.

OCT 1 1986

19. REVIEWER NAME	SIGNATURE	DATE COMPLETED
G. Poochikian, Ph.D.		9/19/86

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