CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 20-583

CLINICAL PHARMACOLOGY and BIOPHARMACEUTICS REVIEW(S)

NDA 20-583 SUBMISSION DATE: March 31, 95

Loteprednol Etabonate
(Lotemax® Ophthalmic Suspension)

Pharmos Corporation
2 Innovation Drive
Suite A
Alachua, FL 32615

REVIEWER: Ene I. Ette, Ph.D., FCCP, FCP

TYPE OF SUBMISSION: NME

BIOPHARMACEUTICS REVIEW

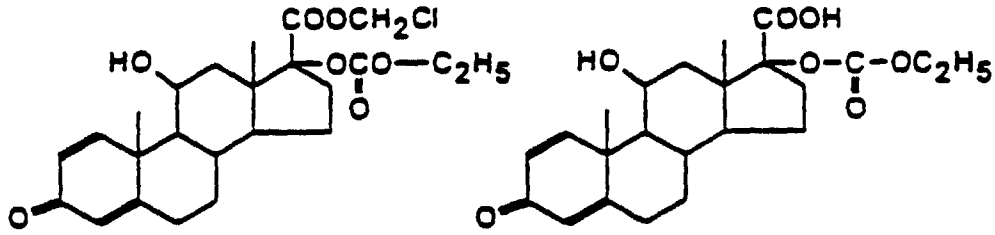

Fig. 1 Loteprednol Etabonate PJ-91

For study P-5604:120, lot 430451 was used as the active lot with lot 373471 used in the placebo treated patient, and the composition was as follows:

Raw Material	Amount Required	Units	Quantity (mg/ml)
Loteprednol etabonate (sterile)			
Povidone USP			
Benzalkonium chloride solution NF			
Edetate disodium USP			
Glycerin USP			
Tyloxapol USP			
Purified water USP			
Sodium hydroxide NF	adjust pH		adjust pH
Hydrochloric acid	adjust pH		adjust pH

This formulation was used for the Phase III clinical trials.

4. COMMENT:

1. Pharmacokinetic and pharmacodynamic measurements should have been expressed as mean ± SD and mean ± SE.

5. RECOMMENDATION:

The Division of Pharmaceutical Evaluation III recommends that the pharmacokinetics section of the NDA is acceptable. Please convey the above comments to the Sponsor.

11/14/95

Ene I. Ette, Ph.D., FCCP, FCP
Pharmacometric staff

FT initialed by F. Pelsor, Pharm.D.....
Biopharm Day attendees on 11/3/95: N. Fleischer, M. Mehta, M. L. Chen, F. Pelsor
cc: NDA 20-583 (Orig.), HFD-540, HFD-855 (Ette), HFD-880 (Pelsor, Fleischer), HFD-340 (Vishwanathan), Chron, Division, Drug, Reviewer's Files, HFD-19 (FOI)