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AUTHORS

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Commercial Relationships Disclosure (Abstract): David Bourne: Commercial Relationship: Code N (No Commercial Relationship) | Sunil Vooturi: Commercial Relationship: Code N (No Commercial Relationship) | Jiban Panda: Commercial Relationship: Code N (No Commercial Relationship) | Stephanie Choi: Commercial Relationship: Code N (No Commercial Relationship) | Hyewon Kim: Commercial Relationship: Code N (No Commercial Relationship) | Sarath Yandrapu: Commercial Relationship: Code N (No Commercial Relationship) | Uday Kompella: Commercial Relationship: Code N (No Commercial Relationship)
Study Group:

ABSTRACT

TITLE: Effect of Particle Size and Viscosity of Ophthalmic Suspensions on Ocular Bioavailability
ABSTRACT BODY:
Purpose: To determine the effect of particle size and viscosity of budesonide suspensions on topical ocular bioavailability.
Methods: Budesonide nanosuspension was prepared by homogenization followed by microfluidization. Budesonide microsuspension was prepared by homogenization. Viscosity of the formulations was adjusted using different grades of hydroxyl propyl methyl cellulose (HPMC). Particle size was measured using a Zetasizer Nano ZS. Viscosity was measured using a Brookfield cone and plate viscometer. Budesonide was analyzed using an LC-MS/MS method, with a C-18 column, triamcinolone internal standard, and a linear gradient. Budesonide suspensions were dosed topically to New Zealand white rabbits, in a 30 µL eye drop, placed in the cul-del-sac of both eyes. Each animal was euthanized at one of six times points and aqueous humor was removed from each eye and stored frozen until analysis. Cmax and tmax values were determined by inspection and the AUC (0-6 hr) values were determined using the linear trapezoidal rule. These data were further analyzed using ANOVA and Duncan's multiple range test for significance at $p = 0.05$. Bioequivalence was further evaluated using a bootstrap method.
Results: 1) Nanosuspension (~700 nm) with low viscosity (4.9 cPs), 2) microsuspension (~2000 nm) with low viscosity (4.9 cPs), and 3) microsuspension (~2000 nm) with high viscosity (53 cPs) were prepared and compared for bioavailability. The average Cmax values were 0.26, 0.22, and 0.35 µg/g and tmax values were 0.77, 0.75 and 1.1 hr, respectively, for suspensions 1, 2, and 3. The AUC(0-6 hr) values were 0.73, 0.53 and 0.95 µg.hr/g, respectively. Bootstrap analysis indicated that the 90% confidence intervals of the ratio of AUC (0-6hr) values were 0.605 - 0.991 (2 vs 1), 1.026 - 1.766 (3 vs 1) and 0.465 - 0.702 (2 vs 3), respectively.
Conclusions: The three suspensions assessed were not bioequivalent. An increase in viscosity improved the bioavailability of budesonide dosed as microsuspensions.
(No Image Selected)

DETAILS

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AWARDS: