



**A COMPARATIVE, RANDOMIZED, DOUBLE BLIND, PARALLEL GROUP AND NON-CROSSOVER, MULTICENTRIC CLINICAL STUDY WITH ALCAFTADINE EYE DROPS OR OLOPATADINE HYDROCHLORIDE EYE DROPS IN SUBJECTS SUFFERING FROM ALLERGIC CONJUNCTIVITIS.**

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### BACKGROUND

This study was designed to evaluate the efficacy, safety and tolerability of Alcaftadine Eye Drops 0.25% w/v in comparison with Olopatadine Hydrochloride Eye Drops 0.2% w/v in subjects suffering from Allergic Conjunctivitis. The main objective of this study was to compare subjects-perceived relief from the symptoms of ocular itching, conjunctival redness, tearing (watery eyes), eyelid swelling and eye discharge and chemosis.

### METHOD

It was a comparative, randomized, double blind, parallel group, non-crossover, active control multi-centric clinical trial conducted in 9 centers across India in patients with signs and symptoms of allergic conjunctivitis. The recruitment period was from Dec 02, 2015 to May 13, 2016. It was 2 staged study where patient were randomized in the ratio of 1:1. In first and second stage, the total numbers of patients (aged 18 – 60 years) included were 104 and 100 respectively. All the subjects were advised to instil one drop of either Alcaftadine or olopatadine as per randomization. The treatment continued for 14 days with periodic follow-up on 3rd, 7th and 14th day from start of treatment.

### RESULTS

The current study showed the mean change in ocular itching and Conjunctival Redness Score from baseline to visit 4 for Alcaftadine (n=103) and Olopatadine (n=101) as (-2.51,-2.27 P=0.0540) & (-2.08,-1.95 P= 0.3959) respectively. There were 28 clinical adverse events reported (Alcaftadine: 13, Olopatadine: 15) which were mild in nature.

### CONCLUSION

Alcaftadine proved to have marginal superiority in all primary efficacy variables and equally safe and efficacious when compared with Olopatadine.

### Funding

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