ABSTRACT

Timolol Maleate is a β-adrenergic blocker, widely effective in lowering intraocular pressure (IOP) associated with open-angle glaucoma. In the present research work, Timolol Maleate *in situ* gelling systems were prepared using gelrite alone and with Sodium alginate in combination with HPMC E50LV. The formulations prepared were evaluated for several parameters like drug-polymer interaction, gelling time, clarity, pH measurement, drug content, *in vitro* drug release, viscosity, sterility and ocular safety or eye irritation.

The prepared formulations were in liquid state and exhibited low viscosity and by addition of simulated tear fluid caused the solutions to transform into gel with high viscosity. Among the formulations, G6 (gelrite) and A6 (sodium alginate) were selected as the best formulation as it fulfilled all the criteria. The drug release of G6 and A6 extended upto 7 h period.

Two months of stability study were carried out at 40 ± 2°C / 75 ± 5 % RH for the best selected formulations. The results showed that there were no significant changes in all the parameters evaluated for gelrite batch (G6) but sodium alginate batch (A6) was discarded because it produced haziness in the 1st month of storage in stability chamber.

Finally, based on the clarity of the prepared formulation, G6 was evaluated for eye-irritation study in rabbits by Draize technique. The results of the study showed that the scores scored were less than the maximum total score indicating there was no irritation to the ocular tissues and hence the formulation was safe.

Comparison of the best formulation was done with marketed formulation (eye drops) which showed that the developed system is a viable alternative to conventional eye drops.

Keywords: Timolol maleate; *In situ* gelling systems; Viscosity; Gelrite; Sodium alginate; Glaucoma; Eye-irritation.