

Formulation of Thermosensitive *in situ* Otic Gel for Topical Management of Otitis Media

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Shau, *et al.*: *In situ* Otic Gel for Topical Management of Otitis Media

Antibiotics and antiinflammatory agents are the primary and main therapeutic categories in the treatment of otitis media. One of the simpler and feasible approaches of minimizing the problem of repeated use and subsequent resistance is development of sustained release formulation. Therefore, the present investigation aimed to develop a sustained release *in situ* gel formulation containing combination of broad spectrum antibiotic and antiinflammatory agents for the management of otitis media. The prolonged release is achieved by phase transition of Poloxamer 407 (*in situ*) from sol to gel at a physiological temperature in combination with viscosity imparting agent Natrasol 250 and Klucel HF. The formulation P3N3 (19% w/v Poloxamer 407, 1.5% w/v Natrasol 250) and P3K3 (19% w/v Poloxamer 407, 1.5% w/v Klucel HF) showed mucoadhesive strength $37.17 \pm 0.32 \times 10^3$ and $38.12 \pm 0.13 \times 10^3$ dyne/cm², respectively, and gel strength 2.1 and 2 cm, respectively. Both these formulations indicated good drug content and viscosity besides a good gelling ability. The *in vitro* diffusion has demonstrated prolongation of release of both the drugs over a period of 8 h.

Key words: Otitis media, *in situ* gel, Poloxamer 407, phase transition

Otitis media (OM) is the accumulation of fluids in the middle ear, with or without the symptoms of inflammation. The infection is caused by dysfunction or obstruction of eustachian tube and is most commonly diagnosed in children under the age of two^[1]. OM is a major health problem and occurs with high incidence and prevalence in both developed and developing countries^[2]. The microbiology of OM differs with *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*, the most commonly isolated pathogens responsible for majority of infections^[3]. The burden of otitis media is particularly heavy for children in the areas of the world in which access of medical care is limited^[4]. Infants with severe and recurrent OM with effusion are at a risk of problems in behavior and development of speech, language and cognitive ability^[5]. In addition to this otitis media is responsible each year for more than 50 000 deaths in children younger than 5 y of age^[6]. Among the south-Asian countries, a prevalence rate in India is high (7.8%)^[7].

Treatment modalities for otitis media infection include use of antibiotics and pain relievers in

the forms of ear drops, ointments, insufflations. The surgical procedure is only for the cases where the medication is non-responsive. It includes insertion of small ventilation tube in the ear drum to improve air flow and fluid back up in the middle ear.

One of the limitations of intra tympanic (IT) drug delivery is that drug is rapidly lost from the middle ear by a number of processes. Ear drops have drawback of shorter residence time in ear, while semisolid preparations have disadvantages such as difficulty in application. The middle ear mucosa is ciliated, which aids the removal of fluids from the compartment. In order to provide a prolonged delivery of drug to the cochlea, it is therefore necessary to control the drug loss from the middle ear, specifically

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