OBJECTIVE OF WORK

Oral and oropharyngeal candidiasis is an opportunistic, infectious condition caused by a ubiquitous, saprophytic fungus of the genus Candida, the most common of which is candida albicans. Prescription drug data have indicated a remarkable increase in the frequency of the disease during the last two decades. Fungal opportunistic infections, including oral and oropharyngeal candidiasis is a major cause of morbidity and mortality in cancer patients. Many factors can predispose a patient to oral and oropharyngeal candidiasis, the most significant of which is the infection associated with AIDS immunosuppression. General debilitation, poor oral or dental hygiene, and ill-fitted dentures are some of the other predisposing factors responsible for the cause of Candidiasis in the oral cavity. Also, those individuals afflicted with xerostomia, diabetes mellitus, and patients receiving chemotherapy are high risk for opportunistic fungal infections.

Conventional formulations (EXISTING CONDITION) for local oral delivery are principally lozenges, mouthwashes, mouth-paints, oral gels, pastes and suspensions. One of the major limitations (PHARMACOTHERAPEUTIC GAP) associated with oral mucosal route of administration is the lack of dosage form retention at the site of absorption. Consequently, bioadhesive polymers have extensively been employed in oral mucosal drug delivery systems in the form of adhesive patches adhesive films, adhesive tablets and oral mucosal gels. Oral mucoadhesive films (IDEAL CONDITION) are highly flexible and ensure more accurate dosing of the drug compared to gels and ointments. Moreover, oral mucoadhesive films are suitable for protecting wound surfaces, thus reducing pain and increasing the treatment effectiveness.

Generally, systemic administration of antimycotics by mouth or intravenous route has been used to treat existing mycotic infections. However, long term systemic antimycotic therapy in high doses is undesirable for treatment of oral infections due to potential side effects. Therefore, to minimize these adverse effects and the ominous risk of drug resistance, topical therapy should be considered the first-line candidate for the treatment of initial or recurrent cases of uncomplicated oral and oropharyngeal candidiasis, in additional to AIDS related oral cavity manifested fungal diseases.
Hence the rationale of the proposed work is to formulate, develop and evaluate Hydrogel based mucoadhesive sustained release drug delivery system of Econazole Nitrate (a potent imidazole antifungal) (ECN) and Nystatin (a polyene antifungal antibiotic) (NYS), potent anti-candidal agents. Hydrogel based mucoadhesive property of the mucoadhesive hydrogel film (MHF) ensure the biocompatibility and increase the retention time whereas sustained release part of the system decrease the frequency of application of the delivery system. So all the problems discussed above with the therapy of oral and oropharyngeal candidiasis can be solved.

In the light of the above cited objectives and background (preamble), the principal objective of work is to formulate mucoadhesive films containing small dose of antifungal drugs like Econazole, Miconazole, Nystatin, Fluconazole or Itraconazole etc for topical treatment of oral candidiasis to ensure satisfactory drug level in the mouth for prolonged duration of time and to reduce side effects and possibility of drug interaction encountered during systemic therapy. The prepared formulations would be evaluated through in vitro and in-vivo antifungal activity on Candida Albicans.