Title: <u>Development Developing</u> a Gum Base Formulation for Nystatin, ; a New Drug Delivery Approach for Treatment of Oral Candidiasis.

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Abstract:

The purpose of this work is to develop a new formulation of -nystatin using chewing gum as a drug delivery system to optimize the drug release rate in relation order to improve the desired efficacy in the site of action for treatment treating of patients with oral candidiasis. Medical chewing gum is a pleasant and highly convenient method of administration for almost all groups of patients. Nystatin is an antifungal drug with very low solubility in water. When the drug is formulated alone in chewing gum, its release rate was very low. To increase its aqueous solubility and release rate from the chewing gum, polyethylene glycol 4000 and 400 were used as solubilizing agents. Nystatin formulations were prepared as a solid dispersion with PEG-4000 and simple dispersion with PEG-400 and incorporated into the chewing gum. The results of the solubility studies with shake-flask method showed ind ated that the apparent solubility of nystatin increased significantly up to 4.3 mg/ml and 2.6 mg/ml with PEG-4000 and PEG-400 respectively in in phosphate buffer, pH: 6.8, . In vitro dissolution studies were performed by a mastication device, and respectivel demonstrated that the nystatin-PEG4000 solid dispersion formulation through the chewing gum had extended and complete release rate. The obtained results of obtained our study showedhere suggested that the nystatin chewing gum was more efficacious than the commercial nystatin suspension, and the optimized formulation had also good stability.

Keywords: nystatin, chewing gum, PEG-4000, apparent solubility, solid dispersion, dissolution profile, oral candidiasis.



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