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Formulation of a chewing gum for treating oral candidiasis

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Fungal infections have become major causes of morbidity and mortality among immuno-compromised patients. Oral candidiasis is a fungal infection caused the opportunistic pathogen named *Candida albicans*. Conventional available treatments for oral candidiasis include topical antifungal azoles such as Miconazole, Amphotericin B and Nystatin. Miconazole, in various formulations (gels, lozenges or mixtures) for local application, is an effective antimycotic drug for treating oral candidiasis. However the increase of resistant micro-organisms to conventional treatment is becoming a challenge, researchers are trying to identify potential drugs and alternatives treatments with better and improved therapeutic effects and fewer adverse effects. Essential oils have been used for the treatment of several diseases. They possess antibacterial, antifungal, antiviral and antiseptic activities. Certain essential oils have been shown to have antifungal activity or reduce the risk of fungal infections. In this study, a selection of essential oils was made and evaluated based on their anti-candidal activity, organoleptic properties, availability and minimum inhibitory concentration for possible inclusion and formulation into the chewing gum as an active pharmaceutical ingredient. Preformulation studies were conducted to identify suitable excipients and evaluate physicochemical compatibilities of the actives with selected excipients. From three placebo formulations obtained from the gum base manufacturer, preliminary development of the formulation was done. A series of formulations were developed by varying different tablet components. The active pharmaceutical ingredients (API's) were included in the gum core both at 2% (w/w) of the MCG composition. The formula was subjected to scale-up. Produced MCG's from the scale-up were film coated to improve stability. Finished products were subjected to post-compression evaluation including *in vitro* release of the API's from the dosage form. This study proved that it is possible to develop a medicated chewing gum with a combination of essential oils as active substances for the effective treatment of oral candidiasis.

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