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Preparation and evaluation of nicotine slow release mucoadhesive film for nicotine replacement therapy

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Background and Aims: Nicotine replacement therapy (NRT) with gradual decreasing the amount of nicotine is one of the smoking cessation methods. Nicotine dosage forms on the market are including gum and skin patches. Mucoadhesive formulations are the novel drug delivery systems that can be used for NRT. Mucoadhesive nicotine film (MNF) when placed in the upper gum, will adhere to mucosa and release the nicotine in a controlled manner. MNF will meet the immediate and long-term need of the individual to the nicotine, and could decrease his/her dependency on smoking.
Methods: The mucoadhesive films were prepared using different conventional bioadhesive polymers such as HPMC, PVP, Na Alginate, Ethyl cellulose and Eudragit RL100; and Glycerin as the plasticizer for formulations of nicotine hydrogen tartrate, which is more stable form of nicotine. The pharmaceutics characteristics of film include rate of drug release and in vitro adhesion, disintegration time and swallow amount were evaluated.
Results: The formulations make with PVP have improved adhesion properties and formulation with HPMC6cps or Na.Alginate released nicotine in the average less than an hour. Drug release from formulations contains HPMC15000cps take long about 120 minutes, but in formulations contains Eudragit were within 4.5 to over 6 hours.
Conclusions: The best formulation with suitable adhesion and rate of release contains Eudragit RL100 and Glycerin that release nicotine for 5 hour.

Keywords: Mucoadhesive; Film; Nicotine; Smoking cessation; Slow release