

FORMULATION AND EVALUATION OF ORODISPERSIBLE FILMS OF NITROGLYCERIN

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Background: The aim in present study is to develop Oral dispersible Films which can be use for either buccal or sublingual. Oral film is one of the new dosage forms and fast dissolving drug delivery system. They are used as an alternative traditional dosage forms (tablets and capsules) for pediatric and geriatric patients who experienced difficulty in swallowing traditional oral dosage forms. Buccal drug absorption through oral mucosa is greater than that of the skin regarding to the permeability; however, it is less than that of the intestine. Therefore, the oral-mucosa delivery act as a good site for the absorption of drugs that have poor dermal absorption and for drugs suffer from first pass metabolism [1]. Sublingual absorption through sublingual route however, 3-10 times greater than oral route. Oral dispersible film of loaded with nitroglycerin using a novel hydroxypropyl starch polymer were prepared.

Methods: The film was prepared by a solvent casting method in which hydroxypropyl starch was used as a film forming polymer. Briefly, sorbitol and other excipients were added to distilled water followed by adding polymer and stirred that for 5 minutes. The resulting oral film where evaluate using in vitro disintegration time. Petri dish with 6.5 cm was used to determine the disintegration time, which is similar to the sublingual area with diameter 3-4 cm. Moreover, the volume of liquid is comparable to volume of saliva. The time that the film takes before breaking down was recorded as a disintegration time.

Results: The disintegration time of the oral dispersible films was an average of 25 second which is nearly 8 times faster disintegration than sublingual tablet (results not shown). To mimic different saliva flow rate in the oral cavity, the retained drug in the formulation using different flow rate of artificial saliva. There is a significant different in drug release has been obtained from different flow rate. The drug retained indirectly proportion with flow rate. Zero percentage of drug retained after 15 min with flow rate 2 mL/min where about ~ 20 % of drug been retained at 0.5 mL/min rate.

Conclusions: In this study we have demonstrated that the prepared oral film disintegration time efficient and the release profile of nitroglycerin from Hydroxypropyl starch film is dependent on the saliva amount and flow rate in the oral cavity. This highlights the potential application of hydroxypropyl starch polymer in formulation fast dissolving oral film. Furthermore, this work illustrates the importance of understanding that subtle differences in patient physiology could impact on the release from such formulations, and a realization of this is very important especially when designing medicines for elder group of patients.