

Development and Efficacy Assessment of an Enteric Coated Porous Tablet Loaded with F4 Fimbriae for Oral Vaccination against Enterotoxigenic Escherichia coli Infections

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Abstract : Enterotoxigenic Escherichia coli (ETEC) infection is one of the major causes contributing to the development of diarrhoea in adults and children in developing countries. To date, no preventive/treatment strategy showed promising results, which could be due to the lack of potent vaccines, and/or due to the development of resistance of ETEC to antibiotics. Therefore, in the present investigation, a novel porous Sodium Alginate (SA) tablet formulation loaded with F4 fimbriae antigen was developed and tested for efficacy against ETEC infections in piglet models. Pre-compression parameters of the powder mixes and post compression parameters of tablets have been evaluated and results were found to be satisfactory. Loading of F4 fimbrial antigens in to the tablets was achieved by inducing pores in the tablets via the sublimation of camphor followed by incubation with purified F4 fimbriae. The loaded tablets have been coated with Eudragit L100 to protect the F4 fimbriae from (a) highly acidic gastric environment; (b) proteolytic cleavage by pepsin; and (c) to promote subsequent release in the intestine. Evaluation of developed F4 fimbrial tablets in a Pig model demonstrated induction of mucosal immunity, and a significant reduction of F4+ E. coli in faeces. Therefore, F4 fimbriae loaded porous tablets could be a novel oral vaccination candidate to induce mucosal and systemic immunity against ETEC infections.

Keywords : porous tablets, sublimation, f4 fimbriae, eudragit l100, vaccination

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