

Abstract

The aim of the study is to develop an oral delivery system of BCG vaccine. Two important goals are described as following: (1) to develop an oral vaccine delivery system to carry BCG vaccine in enteric film in order to protect BCG vaccine from the attack of gastric acid and deliver onto the intestinal tract of vaccinated subjects for eliciting mucosal immune response; (2) to establish a small scale preparing method of oral BCG vaccine delivery system for applying in the development of industrial technology.

The enteric polymer(a derivative of methyl cellulose)and plasticizers were dissolved in methylene chloride to prepare enteric films. The physicochemical properties of prepared films, including thickness, leakage and solvent residual, were evaluated. The delivery systems of BCG vaccine were further studied in disintegration test for optimizing formulation factors. The investigated oral BCG vaccine delivery systems were conducted following studies: (1) *in vitro* study: stability and BCG potency, (2) *in vivo* study : Enzyme-Linked Immunosorbent Assay (ELISA) and the Mantoux Test.

From preliminary study results, we had established a technique to prepare enteric film which was successfully applied to prepare oral BCG vaccine delivery system in small scale. The preparation still maintained about 10% and 25% of BCG potencies in -20 for 2 months or in room temperature(25) for 24 hrs. From *in vivo* study, the prepared oral BCG vaccine delivery system could elicit mucosal immune response by the using the Mantoux test, which might be potentially developed as an oral vaccine preparation for controlling tuberculosis.

Key words : Oral BCG Vaccine, enteric delivery system, Mantoux Test, BCG potency