

Abstract

The project attempts to develop an oral delivery system of BCG vaccine. The project will be proceeded in three years. In the first year, solid dosage forms have been investigated to evaluate the physicochemical properties of developed preparations. Oral vaccine delivery systems are prepared, the release characteristics are determined by in vitro dissolution method. In the second year, the uptake mechanism of intestinal tract for prepared vaccine carrier will be investigated. In addition, formulation factors potentially affecting vaccine delivery systems will be assessed for the establishment of an optimal formulation of oral vaccine preparation. In the third year, the major work is to establish the evaluation method for assessing vaccine stability. Additionally, we intend to develop an animal model to evaluate the therapeutic effect of vaccine preparations. The in-process factors related to the manufacturing procedure will also be evaluated.

In this year, we use biodegradable polymers polylactic acid,(PLA) and poly(lactide-co-glycolide) (PLG) to prepare PLA microspheres and PLG microlamella as carriers for adsorbing BCG vaccine. Carriers with vaccine can be further prepared as granules and capsules for convenience in oral administration. Capsules with enteric coating are prepared to prevent the digest of active vaccine in gastric fluid. Preparations are conducted by in vitro dissolution test to evaluate the protecting capability of enteric coating, vaccine preparations are tested in acidic fluid (pH 1.2) for 2 hrs, following in neutral phosphate buffer solution. Our results indicated that the protecting capability of enteric coating is enhanced as increasing the coating time. The capsule is still maintained intact after 2 hr test in simulated gastric fluid, however, the capsule is rapidly disintegrated to release BCG vaccine in neutral phosphate solution.

Intermediate and semi-final preparations related to preparing vaccine delivery systems are also evaluated by determining BCG potency. In our preliminary test, the prepared semi-final preparation could maintain 8~22% of the activity of BCG.

Overall the results of the first year, we can use biodegradable polymers in the preparation of vaccine carrier for adsorbing BCG. The prepared delivery systems can maintain suitable activity in potency test. BCG vaccine is potentially developed as oral delivery system in the study. Another, the established technique can be applied to other vaccines for the development of oral vaccine

preparations.

Key Word : Oral Vaccines 、 BCG Vaccines 、 Biodegradable Polymers 、 Vaccine Carriers