AIMS AND OBJECTIVES

Over the past several decades, there has been an enormous increase in the strategies for novel vaccines and improvement of existing vaccines.

The aims of the present study are:

1. To evaluate the potential use of chitosan and albumin microspheres as a delivery system for the oral delivery of hepatitis B surface antigen.

2. To study the effect of protease inhibitors, such as aprotinin and bacitracin on oral delivery of hepatitis B surface antigen.

3. To study the effect of the permeation enhancer sodium taurocholate on oral delivery of hepatitis B surface antigen.

4. To compare the immunogenicity of orally administered microencapsulated hepatitis B surface antigen (HBsAg) with intra-muscularly administered HBsAg.

5. To compare the immunogenicity of different oral formulations of microencapsulated hepatitis B surface antigen (HBsAg)

6. To study the effect of different storage conditions on the immunogenicity of orally administered microencapsulated hepatitis B surface antigen.

Objectives of the Study

Immunization has had a tremendous impact on health worldwide, as demonstrated by the global eradication of smallpox, the elimination of poliomyelitis from most of the world, and the elimination of measles in many developed countries. In spite of these successes, significant problems remain to be tackled. Annually, millions of deaths still result from vaccine preventable
diseases, as well as from infectious diseases. There are multiple reasons for this poor coverage, including lack of finances, deficiencies in the immunization infrastructures, and the logistical barriers to distributing vaccines and immunizing populations in remote areas. Improvements in vaccine formulations that make vaccine delivery easier and safer, decrease dependency on the cold chain or reduce the number of immunization interventions needed, could have a significant impact on this area.

First, improved vaccine delivery systems are needed. Ironically, the very act of giving vaccines, most of which are administered by needle and syringe, potentially results in a significant transmission of disease, due to unsafe injection practices in many parts of the world. A second major factor contributing to the incomplete vaccination coverage is the thermolability of vaccines, which requires their continuous storage and transport in a cold chain to ensure their activity at the moment of administration. The logistical difficulties of maintaining the cold chain means that vaccines may either not be available or else may have been exposed to temperatures rendering them less active in remote areas. As described above, improvements to formulations are needed to address factors affecting vaccine coverage. Even if the antigen against which protective immunity is desired can be identified, it is difficult to make a vaccine that induces an immune response at the correct site and that has the required magnitude and immune bias while remaining safe.

The objective of our study was to prepare an oral antigen delivery system for improving the vaccine coverage, reduce dependency on cold chain and prevent transmission of diseases through unsafe injections.