Review Article

Novel Approaches for Oral Delivery of Insulin and Current Status of Oral Insulin Products

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ABSTRACT: Diabetes mellitus is a serious pathologic condition that is responsible for major healthcare problems worldwide and costing billions of dollars annually. Insulin replacement therapy has been used in the clinical management of diabetes mellitus for more than 84 years. The present mode of insulin administration is by the subcutaneous route through which insulin is presented to the body in a non-physiological manner having many challenges. Hence novel approaches for insulin delivery are being explored. Challenges to oral route of insulin administration are: rapid enzymatic degradation in the stomach, inactivation and digestion by proteolytic enzymes in the intestinal lumen and poor permeability across intestinal epithelium because of its high molecular weight and lack of lipophilicity. Liposomes, microemulsions, nanocubicles, and so forth have been prepared for the oral delivery of insulin. Chitosan-coated microparticles protected insulin from the gastric environment of the body and released intestinal pH. Limitations to the delivery of insulin have not resulted in fruitful results to date and there is still a need to prepare newer delivery systems, which can produce dose-dependent and reproducible effects, in addition to increased bioavailability.

KEYWORDS: Insulin; Oral delivery; Challenges; Approaches; Market status

Introduction

Diabetes mellitus is a common disease and its complications are responsible for excess morbidity and mortality, loss of independence, and reduced quality of life (Giriraj KG, 2003; Ahmed I, 2006). Diabetes mellitus is a serious pathologic condition that is responsible for major healthcare problems worldwide and costing billions of dollars annually.

Current routes for Insulin delivery and their problems

The present mode of insulin administration is by the subcutaneous route by which insulin is presented to the body in a non-physiological manner. The subcutaneous administration of insulin has many challenges.

Insulin injected subcutaneously at least twice a day is having many inherent disadvantages include local pain, inconvenience of multiple injections, and occasional hypoglycemia as a result of overdose, itching, allergy, hyperinsulinemia, and insulin lipodystrophy around the injection site. Lastly, clinical trials have shown that even on injectable insulin treatment, a significant percentage of patients fail to attain lasting glycemic control due to non-compliance (Pamnani D, 2008).

Because of these problems, novel approaches for insulin delivery are being explored, including oral, transdermal, nasal, rectal, pulmonary, uterine, and ocular delivery as well as s.c. implants. Delivery options that use dermal, nasal, and oral approaches have been explored (Cefalu WT, 2004; Haak T, 1999). This review describes various oral insulin delivery systems.

Why oral delivery of insulin?

Making needles needless is gaining widespread prominence, to offset the aforementioned disadvantages by oral delivery of insulin. The oral route is considered to be the most acceptable and convenient route of drug administration for chronic therapy. Due to knowledge explosion in the biotechnology industry, extensive investigations are being conducted to achieve successful control of blood glucose by the oral delivery system.