ABSTRACT

Diabetes mellitus is a major global health concern, with limited progress in the development of efficient oral insulin formulations. The current study was designed to assess the physicochemical, biochemical, and therapeutic efficiency of alginate and sericin loaded nanocomposites, which were developed as a protective oral delivery route for insulin. Ionic gelation was used to create the nanocomposites, which demonstrated excellent stability, controlled release, and high encapsulation efficiency in gastrointestinal simulations. Mice with alloxan induced diabetes were used for in-vivo evaluations. Insulin-loaded sericin-alginate nanocomposites administered orally for 21 days preserved body weight and significantly decreased fasting blood glucose levels as compared to the negative control. Blood glucose levels in the NC group increased gradually, from about 210 mg/dL to about 348 mg/dL, while 60 UI INS/60 kg reduced fasting blood glucose level from 220 mg/dL to 115 mg/dL. Significant improvements in liver and kidney function were evident by biochemical study, coupled with restored lipid profiles that showed higher HDL and lower levels of LDL, triglycerides, and cholesterol. Histological analysis revealed normal architecture of pancreatic and liver tissue in treatment groups similar to positive control. It can be concluded from the study that the sericin–alginate nanocomposites are safe, natural, and efficient oral insulin delivery method that can replace traditional subcutaneous injections.

Keywords: Diabetes mellitus, oral insulin administration, nanocomposites, sustained release, glycemic control.