

A novel dissolution media for testing drug release from a nanostructured polysaccharide-based colon specific drug delivery system: an approach to alternative colon media

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Abstract The aim of this study was to develop a novel microbially triggered and animal-sparing dissolution method for testing of nanostructured polysaccharide-based micron granules for colonic drug delivery. In this method, probiotic cultures of bacteria present in the colonic region were prepared and added to the dissolution media and compared with the performance of conventional dissolution methodologies (such as media with rat cecal and human fecal media). In this study, the predominant species (such as *Bacteroides*, *Bifidobacterium*, *Lactobacillus* species, *Escherichia* and *Streptococcus*) were cultured in 12% w/v skimmed milk powder and 5% w/v grade "A" honey. Approximately 10^{10} – 10^{11} colony forming units/mL of probiotic culture was added to the dissolution media to test the drug release of polysaccharide-based formulations. A USP dissolution apparatus 1/1 using a gradient pH dissolution method was used to evaluate drug release from formulations meant for colonic drug delivery. Drug release of guar gum/Endragit PCSOD coated 5-fluorouracil granules was assessed under gastric and small intestine conditions within a simulated colonic environment involving fermentation testing with the probiotic culture. The results with the probiotic system were comparable to those obtained from the rat cecal and human fecal-based fermentation model, thereby suggesting that a probiotic dissolution method can be successfully applied for drug release testing of any polysaccharide-based oral formulation meant for colonic delivery. As such, this study significantly adds to the nanostructured biomaterials' community by elucidating an easier assay for colonic drug delivery.

Keywords probiotic media, colon specific drug delivery, dissolution methodologies, simulated colonic media, microbially triggered drug delivery

Introduction

Colon specific drug delivery systems (CDDS) afford the most advantages for many local treatments of colonic disorders/diseases such as colon cancer and inflammatory bowel disease (which is of two types, ie, Crohn's disease and ulcerative colitis), and other local bacterial infections.^{1–2} The approaches which are commonly used for a drug to reach the colon include a prodrug design approach, a time-dependent system, a pH sensitive polymeric approach, and microflora-activated delivery systems.^{3–4} Among the aforementioned systems, the microflora-triggered delivery systems have been found to be the most promising because specific colonic enzymes degrade the polysaccharide coating for drug release.^{5–7} The main principle of action of microflora-activated systems is enzymatic degradation of polysaccharides (such as chitosan, inulin, guar



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