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(54) Title: A DELAYED RELEASE DRUG FORMULATION

(57) **Abstract:** Delayed release of a drug to the colon is achieved from a delayed release formulation comprising a core and a coating for the core. The core comprises a drug and the coating comprises an outer layer and at least one layer between the core and the outer layer selected from the group consisting of an isolation layer and an inner layer. The outer layer comprises a mixture of a first polymeric material which is susceptible to attack by colonic bacteria, and a second polymeric material which has a pH threshold at about pH 5 or above. The inner layer comprises a third polymeric material which is soluble in intestinal fluid or gastrointestinal fluid, said third polymeric material being selected from an at least partially neutralised polycarboxylic acid and a non-ionic polymer. In embodiments in which the third polymeric material is a non-ionic polymer, the inner layer comprises at least one of a buffer agent and a base. The isolation layer comprises a non-ionic polymer which is soluble in intestinal fluid or gastrointestinal fluid. The outer is applied directly to the inner layer or the isolation layer using a coating preparation formed by combining the first polymeric material in an aqueous medium with a second polymeric material in an organic medium. Advantages of formulations according to the present invention include accelerated release of the drug when exposed to colonic conditions and reduction or elimination of a food and/or alcohol effect on drug release after administration.

