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Formulation and Evaluation of Enteric Coated Tablets of Sodium Diclofenac Utilizing a Polymeric System

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Abstract

Challenges in the formulation of modern enteric coatings have been more and more relying on polymers containing carboxylic acid groups as a functional moiety. The rise in pH level above the point of dissolution causes the ionization of the polymer and, subsequently the release of the drug. The selection of a pH-sensitive polymer with a suitable coating thickness and pH-dependent solubility is crucial. Diclofenac sodium, a non-steroidal anti-inflammatory drug used to treat mild to moderate pain, is also known to cause an increased risk of serious gastrointestinal (GI) adverse events, such as bleeding, ulceration, etc. Therefore, this study aims to develop a formulation utilizing a combined system of anionic copolymers for the formulation of enteric-coated tablets using diclofenac sodium as the prototype drug. In the presented work, Diclofenac sodium was formulated as delayed-release tablets using Opadry YS clear utilized at a 4% weight gain in combination with Acryl-EZE, an aqueous acrylic enteric system utilized at 3 different coating weight gains, 7%, 10%, and 15 %. The data supports the theory that a thicker enteric coat secures a better dissolution rate of Diclofenac sodium.

Keywords: formulation, enteric coated tablets, sodium diclofenac, polymeric system

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