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Investigating the Feasibility of Mefenamic Acid Nanosuspension for Pediatric Delivery: Preparation, Characterization, and Role of Excipients

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Abstract: Molecules with poor aqueous solubility are difficult to formulate using conventional approaches and are associated with many formulation delivery issues. To overcome these obstacles, nanosuspension technology can be one of the promising approaches. Hence, in this study, the feasibility of mefenamic acid (MA) oral nanosuspension was investigated for pediatric delivery by studying the role of excipients and optimizing the techniques. Nanosuspensions of MA were prepared by adopting an antisolvent precipitation method, followed by ultrasonication with varying concentrations of polymers, surfactants, and microfluidics. The prepared nanosuspensions were evaluated for particle size, morphology, and rheological measures. Hydroxypropyl methylcellulose (HPMC) with varying concentrations and different stabilizers including Tween® 80 and sodium dodecyl sulfate (SLS) were used to restrain the particle size growth of the developed nanosuspension. The optimized nanosuspension formula was stable for more than 3 weeks and showed a reduced particle size of 310 nm with a polydispersity index of 0.329. It was observed that the type and ratio of polymer stabilizers were responsive on the particle contour and dimension and stability. We have developed a biologically compatible oral nanoformulation for a first-in-class drug beautifully designed for pediatric delivery that will be progressed toward further in vivo enabling studies. Finally, the nanosuspension could be considered a promising carrier for pediatric delivery of MA through the oral route with enhanced biological impact.

Keywords: drug release; excipients; mefenamic acid; nanosuspension; pediatric delivery; stability

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1. Introduction

Mefenamic acid (MA) (N-[(2, 3-dimethyl phenyl) amino] benzoic acid; Figure 1) is a potent nonsteroidal anti-inflammatory drug (NSAID) that has low oral bioavailability due to poor aqueous solubility and insufficient dissolution [1,2]. The solubility of MA is one of the critical aspects in formulation and development [2]. At present, 40% of new drugs are poorly water soluble and less permeable [3,4]. Pharmaceutically, MA appears as microcrystalline powder with low aqueous solubility and high permeability [biopharmaceutical classification system (BCS) class II drug], which is a major challenge in the clinical application for its pediatric delivery [5].