

Development of a New Oral Orphan Liquid Formulation of Esomeprazole Destined to Pediatric Patients †

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Abstract: Formulation development for the pediatric population is especially challenging since most of the dosage forms available on the market are designed for the adult population. Therefore, inaccurate dosing and lack of treatment adherence are common problems that could hamper proper treatment in this age group. Formulations for the treatment of acid-related disorders are no exception. Hence, we propose the development of a new oral liquid dosage form. For this purpose, two esomeprazole (ESO) suspensions of 2 mg/ml were developed using esomeprazole magnesium trihydrate as an active pharmaceutical ingredient (formulation A) or crushed esomeprazole granules (formulation B). Physicochemical parameters such as ESO content, pH, appearance, resuspendability, sedimentation volume, and viscosity were performed as part of the stability studies. Also, microbiological assays were performed. Physicochemical and microbiological parameters remained within specifications (according to USP) in both formulations for at least 3 months under refrigerated conditions (4 ° C and 40% RH). In conclusion, the two formulations seem promising alternatives to improve oral administration in pediatric patients.

Keywords: esomeprazole; formulation; pediatric.

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Conflicts of Interest

The authors declare no conflict of interest.