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Preparation and Quality Evaluation of Ibuprofen and Diphenhydramine Hydrochloride Orally Disintegrating Tablets

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***SUMMARY*. The present study was designed to evaluate the preparation and quality of ibuprofen and diphenhydramine hydrochloride orally disintegrating tablets. The formulation was optimized with disintegration time and taste as reference parameters by single-factor and orthogonal experiments. Then the hardness, disintegrating time and dissolution were examined. The best prescription was found to contain: ibuprofen 200 mg, diphenhydramine HCl 25 mg, citric acid 30 mg, microcrystalline cellulose 115 mg, mannitol 48.5 mg, polyvinylpolypyrrolidone 40 mg, sodium lauryl sulphate 10 mg, magnesium Stearate 3.5 mg, gum arabic 1.5 mg, aspartame 15 mg, steviosin 1.5 mg, and sodium bicarbonate 10 mg. The orally disintegrating tablets were congruent and smooth with pleasant taste in mouth. The disintegration time was less than 60 s, and more than 80 % of ibuprofen and diphenhydramine HCl were dissolved within 10 min. Consequently, the formulation design is reasonable and the process of preparation is feasible.**

KEY WORDS: Diphenhydramine HCl, Formulation, Ibuprofen, Orally disintegrating tablets.

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