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School of Pharmacy and Pharmaceutical Sciences
Isfahan University of Medical Sciences

Acetaminophen,diclofenac, chlorpheniramine and magnesium trisilicate in one dosage form; oral tablet formulation and physicochemical evaluation

N. Froutan*, P. Khazaeli, M. Pournamdari, Y. Abasi

School of Pharmacy, Kerman University of Medical Science, Kerman,Iran

Background and Aims: Pain is mainly a defensive mechanism of the body. It arises when tissues are injured which in turn it causes the reaction of subject. The most important drugs for the relief and reduction of pain are non-steroidal anti-inflammatory (NSAID) and opioid drugs. However, the use of opioids is accompanied with more adverse effects and more dependency; therefore NSAID drugs are first line choices. This group of drugs is used in combination with the other ones. Among these drugs, diclofenac sodium was chosen combined with acetaminophen, chlorpheniramine maleate and magnesium trisilicate as a preparation with low complication and less interaction during composition. Similar formulations containing these four materials exist in drug market.
Methods: In this study, several formulations for the preparation of tablets containing acetaminophen, diclofenac sodium, chlorpheniramine maleate and magnesium trisilicate was designed. Among the designed formulations, one was eventually selected which contained sufficient amounts of acetaminophen, diclofenac sodium, chlorpheniramine maleate, magnesium trisilicate, lactose, corn starch and polyethylene glycol. The manufactured tablets were evaluated regarding their appearance, weight and content uniformity, hardness, disintegration time and dissolution profile. An HPLC method of analyses was designed, which was capable of determination of three main components of tablets. In this method we used C18 column (250×4.6 mm) filled with OSD coated silica gel with 254 UV detector.
Results: While the selected analysis method had enough accuracy and precision, chosen formulation had acceptable properties considering weight and content uniformity, hardness, disintegration time and dissolution profile. The content release was about 80% in 40 min.
Conclusions: The chosen formulation can be presented in Iranian drug market as individual oral tablet containing acetaminophen, diclofenac sodium, and chlorpheniramine maleate and magnesium trisilicate.

Keywords: NSAIDs; Formulation; Oral Tablet