Complexation of diclofenac sodium with hydroxypropyl beta-cyclodextrins improves its solubility and stability in ampoule solution which is determined by HPLC

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Abstract

Diclofenac sodium is widely used in medicine as anti-inflammatory and antirheumatic agent. The therapeutic dose of this drug is 75 mg by parenteral administration, however, diclofenac sodium is slightly soluble in water, and therefore, it is prepared as 3 ml ampoule contains 25 mg/ml. The available commercial products of diclofenac sodium ampoules have used different types of solubilizing agents as benzyl alcohol which is an irritant in a concentration more than 3% while the other manufacturers used propylene glycol which has toxic impurities. In this work, I tried to prepare diclofenac sodium injection by using hydroxy propyl beta cyclodextrins, a natural and safe excipient in formulation of ampoule solution which formed an inculcation complex compounds with diclofenac sodium, render it very soluble and more stable. The finished product of ampoules were subjected to the stability study by storing the samples at 40°C and 75% RH for six months and the physico-chemical properties of the samples were tested at different periods. The results showed no change in appearance of the ampoules solution along the study time. In addition, a reversed –phase high pressure liquid chromatographic method was developed and applied in studying the behavior and resistance of diclofenac sodium in its solution to the high temperature challenger. The developed HPLC method was proved to be accurate and able to detect the degradation products of diclofenac sodium in solution.

Biography

Kahtan J Hasson is a Pharmacist since 1970 with Master degree from Herriot-Watt University, UK. He is a Lecturer at Al-Rasheed University and an R&D Consultant at Al-Safa Company for pharmaceutical industries, Baghdad.

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