Abstract

Oro-dispersible tablets (ODTs) are solid dosage forms that are designed to be placed in the mouth, allowed to disintegrate in the saliva, and then swallowed without the aid of additional water in less than one minute. One of the benefits of ODTs over conventional tablets is enhanced patient compliance especially for particular classes of patients including geriatrics and pediatrics who have difficulty in swallowing tablets or capsules.

The aim of this study was to develop a simple and inexpensive method of manufacturing ODTs of Prininium Bromide (PBr) and combinations of PBr and Diclofenac Sodium (DeNa) using direct compression method and study the effect of different types and concentrations of superdisintegrants and diluents on the tablets' characteristics.

Preformulation studies including physicochemical properties of the active pharmaceutical ingredients and compatibility were performed. Physical characterization of the prepared powder mixtures and physicochemical evaluations of the prepared tablets were performed. In addition, accelerated stability studies and in vivo taste evaluation of the selected formulae were also carried out.

Formula AMC2, containing 15mg of PBr, 7.5% of Croscarmellose Sodium as superdisintegrant and Avicel® PH102® Mammitol as diluents, has been chosen as the best formula with a disintegration time of 12.7 ± 4.58 seconds, and almost complete drug release after two minutes in pH 6.8 and in Simulated Gastric Fluid (SGF).

Different taste masking techniques were performed to prepare PBr taste masked granules. Prininium Bromide-Eudragit E100 granules prepared by mass extrusion method were found the best in taste masking. The selected taste masked granules E3 were used in the formulation of PBr taste masked formulae.

The best taste masked formulae T3 gave a disintegration time of 45.5 ± 7.7 seconds, and almost complete release of PBr in pH 6.8 and SGF after 10 minutes.

Combinations of PBr (15mg) and DeNa (25mg) were also prepared and evaluated. The combination was successful and the best formula (Comb2) showed a disintegration time of 56.3 ± 2.1 seconds, and about 85.08% of PBr and 77.82% of DeNa was released in phosphate buffer pH 6.8 and 75.05% of PBr was released in SGF after 15 minutes.

Formulation and Evaluation of Prininium Bromide and Prininium Bromide- Diclofenac Sodium Combination as Oro-dispersible Tablets

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This Thesis was Submitted in Partial Fulfillment of the Requirements for the Master's Degree in Pharmaceutical Sciences- Faculty of Pharmacy and Medical Sciences

Deanship of Postgraduate and Scientific Research
Al-Ahliyya Amman University
Jordan
April 2013

Diss 615:13
A396

Rec No: 0000003960
Author: Alghabban Fulla Mohammad B. J.
Title: Formulation and evaluation of prininium bromide and prininium bromide- diclofenac sodium combination as Oro-dispersible tablets.
Publisher: Al-Ahliyya Amman University. Deanship of Postgraduate and Scientific Research. Faculty of Pharmacy Amman, 2013.
ISBN: 40075
Subject: medicine pharmacy.

No. of Copies: 3
CD-ROM: 3