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ORIGINAL ARTICLE

Design of Dual Principles Floating Osmotic Drug Delivery System of Pioglitazone Hydrochloride for Gastro-retention: In Vitro-In Vivo Evaluation

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Abstract

Background This work aimed to design and optimize the gastro-retentive drug delivery system (GRDDS) by employing dual principles, i.e., floating and osmotic for pioglitazone hydrochloride (PGH). PGH is commonly prescribed for chronic type II diabetes mellitus (DM).

Method Floating osmotic drug delivery system (FODDS)–based tablet was prepared to employ a 3^2-full factorial design to investigate the influence of HPMC-K4M and $NaHCO_3$ on floating lag time and in vitro drug release. Furthermore, graphical optimization was carried out to get the optimal combination based on desirability. The excipients-drug interaction was performed by using DSC and FTIR studies.

Results The optimized bath (OF-O) showed floating lag time (s) = 35.55 ± 2.5 and in vitro drug release (%) = 93.27 ± 2.2. The OF-O showed prolonged release of PGH over 8 h in 0.1 N HCl (pH 1.2). The in vivo estimation of buoyancy in human volunteers in fasted and fed conditions revealed that tablets stayed buoyant in gastric fluid for 8 h. The study concluded that the developed formulation could enhance gastric retention and provide prolonged delivery of PGH.

Conclusion The implementation of dual principles further widens the scope of gastro-retentive drug delivery (GRDDS) for prolonging the drug release in the gastric cavity.

Keywords Gastro-retentive drug delivery system · Pioglitazone hydrochloride · Diabetes mellitus · Floating osmotic drug delivery system · Optimization

Introduction

Diabetes mellitus (DM) (type II) is acknowledged as a severe public health threat that has a major influence on life expectancy and healthcare spending. Speedy economic expansions and urbanization are the leading cause of the rising prevalence of diabetes around the globe [1]. Type II DM can be better managed and controlled by oral hypoglycemic agents [2]. Pioglitazone hydrochloride (PGH), an agonist of peroxisome proliferator-activated receptor gamma ($PPAR_\gamma$), works as an insulin sensitizer, improving glycemic management in patients with type II DM [3]. Moreover, PGH is a more commonly given drug for controlling type II DM, particularly in insulin-resistant type II DM patients with a history of cardiovascular disease and dyslipidemia [2, 3]. Patients with chronic conditions, such as those caused by poor lifestyle choices like DM, are usually prescribed drugs on a daily basis. Because these patients may have poor treatment cooperation due to lifestyle variables such as forgetting

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