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Original Article

Development and Evaluation of Matrix Tablet by Taking New Chemicals Combination of Chitosan and Eudragit-l 100

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ABSTRACT

Objective: The objective of this study is to develop extended release matrix tablet by taking mixture of chitosan and anionic polymers and then to study the drug release pattern for a low solubility drug Tramadol Hydrochloride (TH). TH has mean elimination half-life is ~6 hrs and requires dosing every 6 hrs in order to maintain optimal relief of chronic pain. So once-daily extended-release tablets are formulated by taking Chitosan (CS) and anionic polymers Eudragit-L100-55**. Methods**: The tablets were prepared by direct compression method. *In vitro* drug release was carried out under simulated gastric and intestinal condition to achieve drug release more than 20 hrs. Fourier transform infrared spectroscopy (FTIR) study was conducted to study any interaction between dug and ingredients. **Results**: CS and Eudragit-L combination form a Poly Electrolyte Complex which is responsible for extending drug release for low solubility drug. This complex formation is also confirmed by FTIR study. **Conclusion:** Stability studies (40ºC and 75 ± 5%RH) for 3 months indicated that Tramadol hydrochloride was stable in the matrix tablets.

Key words: Chitosan, Eudragit-L100, Tramadol Hydrochloride, Matrix Tablet, FTIR.

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INTRODUCTION

When a drug is freely soluble in water, the judicious selection of release-retarding excipients is necessary to achieve a constant *in vivo* input rate. One of the most commonly used methods of modulating drug release is to include it in a matrix system. Hydrophilic gel-forming polymer matrix systems are widely used in oral controlled drug delivery to obtain a desirable drug release profile, for cost effectiveness, and broad regulatory acceptance.[1-3] Polymer-based monolithic matrix tablets are the most commonly used oral extended-release dosage forms because of pharmaceutical advantages such as economic benefits, relative simplicity of process development and scale-up procedures.[4,5] Polymeric materials which are used in extended-release matrix systems can be classified into as (a) hydrophilic system; (b) erodible system; and (c) insoluble system.[6,7] Even also to achieve desirable release profiles, polymers should be optimized based on their physicochemical properties associated with release mechanisms. Most frequently utilized polymer mixtures can be divided into three type's i.e. first type is combination of non-ionic polymers second type is combination of non-ionic and anionic polymers and third type is the combination of cationic and anionic polymers (e.g., chitosan (CS)–sodium alginate (SA), and CS–xantham gum (XG).[8,9] But use of CS and anionic polymer form a Poly Electrolyte Complex (PEC) between the polycationic chitosan and polyanionic polymers, such as alginate and pectin, and is responsible for better sustained-release of drug matrices than the original hydrophilic polymers.[10,11] Extended release (ER) dosage forms are designed in such a manner so as to allow the enclosed drug available over an extended period of time after its administration. These are controlled drug delivery systems, which release the drug in continuous manner. They release drug by both dissolution controlled as well as diffusion controlled mechanisms. The term matrix indicates a three dimensional network composed of drug(s), polymer(s) and other excipients. Because of simplicity, ease in manufacturing and low costs, matrix preparation has become a popular approach. Drugs are usually embedded in hydrophilic or hydrophobic matrices to exert control on their release.[12,13] To control the release of the drugs, the drug is dispersed in swellable hydrophilic substances and then in an insoluble matrix of rigid non swellable hydrophobic materials or plastic materials. The use of polymers in controlling the release of drugs has become important in the formulation of pharmaceuticals.

Chitosan, a cationic biopolymer, derived from chitin by partial deacetylation. CS has good biocompatibility, biodegradability, low toxicity and relatively low production cost from abundant natural sources,[14-16] and it has been wildly applied as a polymeric drug carrier in the field of pharmaceutics. It is available in 3 different molecular weight forms. In present topic we have chosen low molecular weight i.e. 50 kDa form. However, although chitosan is a very promising biopolymer as a release-controlling agent in drug delivery, it has limited capacity for controlling drug release when used alone due to its easy disintegration characteristics at neutral pH.[17] Thus, combination of CS with anionic polymers as the carrier of oral controlled-release preparations has been suggested.

Eudragit® L 100-55[18] contains an anionic copolymer based on meth acrylic acid and ethyl acryl ate. It is a solid substance in the form of a white powder with a faint characteristic odour. It is effective for enteric coatings with a faster dissolution in the upper GI bowel.

Tramadol is a non-steroidal anti-inflammatory drug, which is used in the treatment of rheumatoid and osteoarthritis. After oral administration, tramadol is rapidly and almost completely absorbed. The mean elimination half-life is ~6 hrs and requires dosing every 6 hrs in order to maintain optimal relief of chronic pain. Consequently, once-daily extended-release tablets have been formulated. Long term treatment with sustained-release tramadol once daily is safe in patients with osteoarthritis or refractory low back pain and is well tolerated. It has the potential to provide patients increased control over the management of their pain, fewer interruptions in sleep, and improved compliance. Tramadol, a synthetic opoid of the amino cyclo hexanol group, is a centrally acting analgesic with weak opoid agonist properties. Tramadol has been proved to be effective in both experimental and clinical pair without causing serious side effects. The usual oral dosage regimen is 50 to 100 mg every 4 to 6 hrs with a maximum dosage of 400 mg/day. To reduce the frequency