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Creation and Assessment of Extended-Release Salbutamol Tablets with Innovative Polymeric Coating in Tablet Formulation

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Abstract

In recent times, modified drug dosage forms offers manifold merits, such as maintain or sustaining constant drug level at the site of action, prevention of peak concentration fluctuation, reduction in dose of drug, reduced dosage frequency, averting the side effects and which in turn availing improved patient compliance. Hence in this current study, an effort has been made to develop a modified drug release by using tablet in tablet technique encompassing novel polymeric coating by using natural and synthetic polymers with Salbutamol sulphate. The inner core tablets were prepared by using direct compression method. It has been observed that the formulation F7 was selected for press coat by using different polymers like HPMC, Ethyl cellulose, Xanthum gum and Guar gum in different ratios among which 1part of Xanthum gum and 1part of Guar gum was optimized based on the lag time (20.75% in 4 hours) and percent of drug release and also further evaluated.

Keywords: Modified release tablets; Novel polymer coating; Salbutamol sulphate; Tablet in tablet; Controlled drug delivery

Introduction

The second-generation drug delivery goal has been the perfection of continuous, constant rate (zero order) delivery of bioactive agents. However, living organisms are not zero order in their requirement or response to drugs. They are predictable resonating dynamic systems, which require different amounts of drug at predictably different times within the circadian cycle in order to maximize desired and minimize undesired drug effects. Due to advances in chronobiology, chronopharmacology and global market constraints, the traditional goal of pharmaceutics (e.g. design drug delivery system with a constant drug release rate) is becoming obsolete. However, the major bottleneck in the development of drug delivery systems that match circadian rhythms (chronopharmaceutical drug delivery system: ChrDDS) may be the availability of appropriate technology [1]. The diseases currently targeted for chronopharmaceutical formulations are those for which there are enough scientific backgrounds to justify ChrDDS compared to the conventional drug administration approach. These include asthma, arthritis, duodenal ulcer, cancer, diabetes, cardiovascular diseases, hypercholesterolemia, ulcer and neurological diseases .

If the organization in time of living system including man is borne in mind, it is easy to conceive that not only must the right amount of the right substance be at right place but also this must occur at the right time [2]. In the last decade numerous studies in animals as well as clinical studies have provided convincing evidence, that the pharmacokinetics &/or the drug's effects -side effects can be modified by the circadian time &/or the timing of drug application within 24 hrs of a day .

Circadian variation in pain, stiffness and manual and manual dexterity in patients with osteo and rheumatoid arthritis have been studied and has implication for timing antirheumatide drug treatment [3]. Morning stiffness associated with pain at the time of awakening is a diagnostic criterion of the rheumatoid arthritis and these clinical circadian symptoms are supposed to be outcome of altered functioning of hypothalamic pitutary adrenocortical axis. Chrono pharmacotherapy for rheumatoid arthritis has been recommended to ensure that the highest blood levels of the drug coincide with peak pain and stiffness. A pulsatile drug delivery system that can be administered at night (before sleep) but that release drug in early morning would be a promising chronopharmaceutic system. Drug targeting to colon would prove useful where intentional delayed drug absorption is desired from therapeutic point of view in the treatment of disease that have peak symptoms inthe early morning such as nocturnal asthma, angina, arthritis [4]. Some orally administered drugs (e.g. Diclofenac, Theophyllin, IbuprofenIsosorbide) may exhibit poor uptake in the upper regions of GIT or degrade in the presence of GIT enzymes. Better bioavailability can be achieved through colon- specific drug delivery. Colonic targeting is also advantageous where delay in systemic absorption is therapeutically desirable .

Circadian rhythms and their implications

Circadian rhythms are self-sustaining, endogenous oscillation, exhibiting periodicities of about one day or 24 hours. Normally, circadian rhythms are synchronized according to the bodys pacemaker clock, located in the suprachiasmic nucleus of the hypothalamus.

The physiology and biochemistry of human being is not constant during the 24 hours, but variable in a predictable manner as defined by the timing of the peak and through of each of the bodys circadian processes and functions. The peak in the rhythms of basal gastric and secretion, white blood cells (WBC), lymphocytes, prolactin, melatonin, eosinophils, adrenal corticotrophic hormone (ACTH), follicle stimulating hormone (FSH), and leuteinizing hormone (LH), is manifested at specific times during the nocturnal sleep span . The peak in serum cortisol, aldosterone, testosterone plus platelet adhesiveness and blood viscosity follows later during the initial hours of diurnal activity.

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Materials and Methods (Formulation of core tablets by direct compression)

Materials

The materials used in the formulation of the core tablets included micronized fluconazole, pharmaceutical grade excipients such as microcrystalline cellulose (MCC), lactose monohydrate, croscarmellose sodium, and magnesium stearate. All materials were sourced from reputable suppliers and were of analytical grade.

Methods

Preparation of core tablet blend

Accurate quantities of micronized fluconazole, MCC, and lactose monohydrate were weighed according to the formulation requirements.The weighed materials were thoroughly mixed using a suitable blending technique to ensure uniform distribution of the active ingredient and excipients.

Addition of disintegrant

Croscarmellose sodium, a disintegrant, was added to the blend in the calculated amount and mixed again to ensure homogeneity.

Lubrication and final blending

Magnesium stearate, a lubricant, was added to the blend, and a final mixing step was performed to achieve uniform lubrication of the particles.

Direct compression

The uniformly blended core tablet mixture was then transferred to a tablet press equipped with appropriate tooling.

The mixture was compressed using the direct compression method to form tablets of the desired size and hardness.

Tablet evaluation

The produced core tablets were subjected to various quality control tests to assess their physical characteristics, including hardness, friability, and weight variation. Disintegration and dissolution tests were conducted to evaluate the tablet's disintegration time and drug release profile.

Characterization of micronized fluconazole

The micronized fluconazole used in the formulation was characterized for particle size using techniques such as laser diffraction or microscopy [5-8]. Surface morphology and crystal structure of micronized fluconazole were examined using scanning electron microscopy (SEM) and X-ray diffraction (XRD), respectively.

Statistical analysis

The data obtained from tablet evaluation and characterization were analyzed statistically using appropriate methods to determine the mean, standard deviation, and significance of any observed differences.

Conclusion

The formulation of core tablets by direct compression using micronized fluconazole and selected excipients was successfully executed. The tablets were characterized and evaluated to ensure their quality, disintegration, and dissolution behavior. This method provides a straightforward approach to creating dosage forms that can potentially enhance the effectiveness of micronized fluconazole against Candida albicans and Aspergillus niger.

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