ABSTRACT

The modified release drug design of zolpidem tartarate was well developed to keep effectively plasma concentrations during the 3 – 6 h post-dosage type interval, with respect to the middle part of the typical interval of sleep. In this study, an attempt was done to formulate biphasic release of zolpidem tartarate for sleep maintenance and for those people who do not maintain the recommended sleep.

The main objective of present work was to design and evaluate modified releasing pellets of drug, zolpidem tartarate, in respect to increase patient compliance and therapeutically benefits.

The modified releasing pellets were made by the sub-coating with sodium bicarbonate and hydroxyl propyl methyl cellulose which was utilized to keep the spheres in stomach for long time. To get modified release of active pharmaceutical ingredients from the pelletizing process, they were coated with methacrylic acid co-polymer (Eudragit NE 40D). Hence sodium bicarbonate, hydroxyl propyl methyl cellulose and eudragit NE 40D are the key ingredients of this dissertation work. Concentration of sodium bicarbonate, hydroxyl propyl methyl cellulose and eudragit NE 40D in coating suspension was optimized by initial studies and factorial design. The procedure based optimization analysis also perform to optimize process factors like product temperature and spraying rate to improve physical parameters and micromeritic characteristics of spheres by preliminary data.

The pellets were evaluated for physical factors like bulk and tapped density, appearance, hausner’s ratio and angle of repose. The pellets were also evaluated for drug content, friability factors and In-vitro drug release profile. The final data of all the tests performed, were found satisfactory.

Based upon data it was summarized that the release of zolpidem tartarate for 10 h. can be taken by utilizing optimum concentration of hydroxyl propyl methyl cellulose, eudragit NE 40D and sodium bicarbonate as well as by utilizing optimum processing factors like product temperature and spray rate.