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Studies on the influence of formulation and processing factors on the drug release from multiparticulate systems

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New technologies and processes are being developed for existing and new drug molecules to prepare sustained release (SR) and controlled release (CR) dosage forms. Multiunit forms such as pellets offer significant advantages such as better control over drug release and less chances of dose dumping. In the present work, pellets of furosemide (as a model drug) are prepared by extrusion and spheronization. It belongs to BCS class IV drugs which have poor solubility. Since, furosemide exhibits low solubility in gastric fluids to initiate a prompt release from the pellets, a novel approach of incorporating the inclusion complex of furosemide in sulfobutyl ether cyclodextrin in the pellets was employed. Inclusion complex is prepared by kneading method. The utility of almond gum as a binding agent in extrusion and spheronization was investigated. Compared to pellets prepared by employing microcrystalline cellulose, the pellets made by using almond gum were found to be more uniform in size and exhibited a more controlled release spread over 12 hours. The influence of various processing parameters such as speed of extrusion, rpm of spheronizer and time of operation was studied. The characteristics of pellets such as size, size distribution, and shape and drug release are influenced by formulation and processing variations. The drug release data showed a good fit into both Higuchi and Korsmeyer - Peppas equations. The differential scanning calorimetry and infrared spectroscopy (IR) studies revealed that there are no interactions between furosemide and almond gum. The x-ray diffraction studies indicated that the drug furosemide existed in amorphous state in the inclusion complex. The scanning electron microscope (SEM) images of pellets showed that the pellets have spherical shape and their size depended on amount of almond gum employed. The details of experiments performed and results of the investigations will be presented.