Extend Abstract

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Orthopaedics-2021 Formulating extended release drug pellets using CPS™ technology

A Review Article- Neha Chava*

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Producing pellets using Glatt's patented (Complex Perfect Spheres) CPS™ technology has been recognized as one of the most efficient direct pelletization processes which has recently gained a great deal of attention because of its quick processing time, high drug loading, and its ability to yield a wide range of mean particle sizes with narrow distributions. The pellets can be filled in capsules, or compressed in tablets or packaged in sachet as the final dosage form. Traditionally, mixture of active pharmaceutical ingredients (APIs) and inert cellulose substrates are directly pelletized in the CPS™ processor to formulate drug loaded pellets which are subsequently coated using controlled release polymers in Wurster fluidbed processor to achieve the desired drug release profile. The purpose of the study was to develop a unique modified release pellet formulation which can be manufactured using the direct pelletization process in the CPS™ insert and thus eliminate the complicated and time consuming multilayer subsequent coating processes like drug layering, protective, and functional coating to achieve extended release or delayed release profile and thereby significantly reduce the development, processing time and costs.

Hydroxypropyl cellulose (HPC) is used in the formulation as a matrix forming polymer, Microcrystalline Cellulose (MCC) as the diluent and the pellet former and Propranolol as the Model drug. Upon preliminary screening, formulation experiments were performed using the formulation with varying concentration of HPC (10%, 20%, 30%, 40% and 50% w/w) adjusted with MCC for a fixed Propranolol HCl loading of 20% w/w. Each formulation was pelletized in GPCG 1.1 fitted with a CPS-3 inserts. Effect of matrix forming polymer concentration was evaluated based on pellet size, shape, morphology, drug content and dissolution profile. Pellet size was measured using sonic sifter sieving analysis. The surface morphology was evaluated using Scanning Electron Microscopy (SEM).

Formulation composition for the CPS™ pellets manufactured is given in table 1. The formulations utilized a fixed Propranolol HCl loading of 20% w/w. HPC as a matrix forming polymer was added to the formulation composition in an increasing concentration of 10%, 20%, 30%, 40% and 50% w/w. MCC was added in the formulation to form pellets in the CPS™ process. Pellets from all five formulation trials were found to be granular with distinct surface morphology. The particle size of the granular pellets was measured to be within a size range of 500-710 microns as shown in table 2. Pellet growth was observed as shown in figure 2 detected using the digital imaging technique. Surface morphology of pellets was found to be granular observed under SEM as shown in figure 3. Drug content for Propranolol HCl in the granules was greater than 95% w/w of the theoretical drug loading suggesting an efficient loading process. Dissolution profile as shown in figure 4, obtained from the samples indicated that Propranolol pellets containing 50% HPC exhibited a release profile that was extended over the period of 24 hrs.

In the current study, a novel formulation platform was developed using the direct pelletization CPS™ process which exhibited an extended release profile for Propranolol HCl over 24 hours. This one-step direct pelletization approach can be utilized to formulate a modified release multiparticulate dosage form using the CPS™ technology for many APIs especially those which are unstable in coating dispersion and thereby minimizes formulations and process challenges, development time, processing hours and cost involved.