IPORSIP-2000



INDUSTRIAL PHARMACY (IP)

POSTER PRESENTATIONS

POSTER PRESENTATION I. (IP) Droplet Behavior In Film Coating Process

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The objective of this study is to determine the effects of plasticizer type and concentration on droplet size and its spreading properties on aqueous solution of HPMC using direct method.

Hydroxyproylmethylcellulose (HPMC) solutions containing different concentration of poyethylene glycol (PEG) with different molecular weights (300, 400, 600, 1500, 4000, 6000) were prepared. The solutions were sprayed on a surface of polyamide using the following condition room temperature, dichlorodifluoromethane as propellant, 30 m/s velocity and a 40 cm distance between spray gun and substrate. To obtain the geometric mean diameter droplet size (Martin diameter) on a specific region of polyamide surface was measured by optical microscopy (10X). The cumulative frequency percentage undersize was plotted vs log spot size on a probability scale.

The method was shown to be reproducible as no significant difference was observed between the results of repeated experiments by ANOVA (P<0.05). Incorporation of PEG as plasticizer in to the aqueous solution of HMPC resulted, in increase in geometric mean diameter. Comparing different molecular weights of PEG, it was found that geometric mean diameter would increase more (P<0.05) with the inclusion of low molecular weights (300, 400). High molecular weight species of PEG didnot show as much increase in geometric mean diameter as lower molecular weight PEG due to reduction in mol fraction of plasticizer to the polymer. As a consequence, lower number of plasticizer moleculars are available to facilitate movement and spreading of HPMC.

In conclusion, a number of methods such as laser diffractometry have already been used to study droplet siz directly. It was shown in these studies that droplet size would increase as the viscosity of the solution is enhanced.

POSTER PRESENTATION II. (IP)

Investigations On Mefenamic Acid Sustained-Release Tablets With Water-Insoluble Gel

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Sodium alginate is the sodium salt of alginic acid, a natural polysaccharide extracted from marine brown algae. It has been widely used as a food additive and has the ability to form a water-insoluble gel with a bivalent metal. Therefore, sodium alginate has been studied for use as a sustained-release preparation.

Mefenamic acid is a nonsteroidal and anti-inflammatory agent. Available conventional dosage forms are capsules and film-coated tablets where therapeutic intake is three times daily. No commercial sustained release preparation of mefenamic acid exists. Peak plasma concentrations occur about 2-4 hours after ingestion.

In this study, tablets containing different ratios of sodium alginate and calcium gluconate as a bivalent metal were prepared by the dry powder compression method and studied the application of the water-insoluble gel involving the sustained-release of mefenamic acid by permeation of water. The release of mefenamic acid from tablets was evaluated by the dissolution test according to USP XXIII basket method at 50 rpm. Phosphate buffer (pH 7.4, 900 ml) was chosen as dissolution medium. Drug amount in the dissolution medium was determined spectrophotometrically (Shimadzu A-1601) at 285 nm. Kinetic assessments of release data were carried out with a zero-order, first order and Higuchi kinetic models. The release rate was extremely high for the tablets which containing only mefenamic acid and calcium gluconate. On the other hand, sustained-release profile was observed for the tablet containing sodium alginate and calcium gluconate.

POSTER PRESENTATION III. (IP)

Bioequivalence Evaluation Of A Hydrocortisone Tablet Manufactured In Iran

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The bioavailability of a hydrocortisone generic oral preparation (Hydrocortisone 10 mg tablets; Aboureyhan Pharmaceutical Co. Tehran, Iran) has been compared to that of a reference standard preparation (Hydrocorton 10 mg tablets, MSD, USA). The test and reference preparations were administered to 14 healthy volunteers as a randomized two-period, two-sequence crossover design with a 1- week washout period. The endogenous production of hydrocortisone (cortisol) was suppressed using 2 mg dexamethasone given orally 21 hours prior to drug intake. At predetermined time intervals, the serum concentrations of drug were determined using a HPLC method developed and validated in this lab and then, a set of four pharmacokinetic parameters consisting of c_{max} , t_{max} , AUC $_{0\rightarrow12}$ and AUC $_{0\rightarrow\infty}$ were determined for each person. Finally, the statistical t-test on the parameters revealed no significant differences between the results obtained upon administration of two preparations (P>0.05) and also, the 90% confidence intervals of the ratios of all parameters in whole study grou were lied within the range required by FDA (0.8-1.2).