

very few uses in the pharmaceutical area have been reported. The electrospinning technology is well suited to process natural biomaterials and synthetic biocompatible or bioabsorbable polymers for biomedical applications because it is rapid, efficient, and heat free process. The potential applications of microparticles produced by electrospinning include local drug delivery device and surface coating agent. In the present study, we investigated the effects of varying the processing parameters in electrospinning on the PLGA nanoparticles for drug delivery system. We have also demonstrated that the electrospinning could control the initial burst release of tetracycline from PLLA particulates. Tetracycline loaded PLLA particulates with 350-500/ $\mu\text{m}$  diameter for long term drug delivery system were developed in our laboratory. These particulates release tetracycline in therapeutic concentration for 28 days with the initial burst. The initial burst was caused by drug exposed at the surface of particles. To reduce initial burst, we designed surface coating of PLLA particles with PLGA nanoparticles produced by electrospinning method. Scanning electron microscopy (SEM), release test, differential scanning calorimetry (DSC) were used to investigate the structure and morphology of the electrospun PLGA nanoparticles.

[PE1-9] [ 2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function ]

### **In vitro and in vivo evaluation of erdosteine capsule**

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**Purpose.** The purpose of this study is to compare in vitro dissolution characteristics and bioavailability in beagle dog of a hard gelatine capsule containing erdosteine (Yuhan Erdosteine capsule<sup>TM</sup>) with those of commercial product (Erdos capsule<sup>TM</sup>). **Methods.** Yuhan Erdosteine capsule<sup>TM</sup> was prepared using erdosteine 300 mg, lactose, magnesium stearate, and others by powder filling method. The dissolution characteristics of Yuhan Erdosteine capsule<sup>TM</sup> and Erdos capsule<sup>TM</sup> were determined by USP dissolution apparatus 2. The studies were conducted in 900ml of dissolution mediums (pH 1.2, 4.0, 6.8 and water) maintained at 37 °C. Gentle agitation was provided by rotating the dissolution paddle at 50 rpm. A randomized, two way crossover bioavailability study in healthy male beagle dogs was conducted after oral administration of Yuhan Erdosteine capsule<sup>TM</sup>. Blood samples were collected at scheduled intervals and the plasma concentrations of erdosteine were analyzed by HPLC method. **Results & Conclusion.** The dissolution profiles of Erdosteine capsule<sup>TM</sup> were very similar to those of Erdos capsule<sup>TM</sup>.  $AUC_{0-7}$  and  $C_{max}$  of Yuhan Erdosteine capsule<sup>TM</sup> hr/ml and 11.14  $\pm$  3.16 ug/ml, respectively. The relative  $\square$  were 25.56  $\pm$  6.01 ug bioavailability of Yuhan Erdosteine capsule<sup>TM</sup> to Erdos capsule<sup>TM</sup> was 105.5 %, 104.2 %, based on  $AUC_{0-7}$  and  $C_{max}$ , respectively. These results met the bioequivalence criteria of the KFDA guideline. Therefore Yuhan Erdosteine capsule<sup>TM</sup> was revealed to be bioequivalent with Erdos capsule<sup>TM</sup>.

[PE1-10] [ 2003-10-11 09:00 - 12:30 / Grand Ballroom Pre-function ]

### **Study on Polymorphism of Cefotaxime Sodium, Cephadrine, and Ceftriaxone Sodium**

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Investigation of polymorphism has become a requirement in the pharmaceutical industry because the physical properties and bioavailabilities of crystalline drugs depend on their polymorphic form. Two polymorphic modifications and one pseudopolymorphic modification of cefotaxime sodium were prepared by recrystallization in organic solvents under variable conditions. Four polymorphic modifications of cephadrine were prepared by recrystallization. Three polymorphic modifications and one pseudopolymorphic modification of ceftriaxone sodium were prepared by recrystallization. They were characterized by UV spectrophotometer, DSC, TGA and X-ray crystallography. The solubilities of all modifications were checked through the dissolution test. Comparing each solubility of cefotaxime sodium polymorphic forms (by 120 minutes), Form 1 is 99.30%, Form 2 is 85.09% and Form 3 is 45.91%. : Form 1 > Form 2 > Form 3. Comparing each solubility of cephadrine polymorphic modifications (by 120 minutes), Form 1 is 100%, Form 2 is 75.55%, Form 3 is 98.90% and Form 4 is 77.83%. : Form 1 > Form 3 > Form 4 > Form 2. Comparing each solubility of ceftriaxone sodium polymorphic forms (by