

solution. The scaffold of chitosan fibers bonded together by the acid treatment. Surface modification process is like this. Activated chitosan fiber in acid solution and chondroitin sulfate solution mixed and dried. And chitosan fiber were cross-linked by EDC and NHS. Morphology (SEM), FTIR, DSC, cell attachment test, RT-PCR (ALPase, collage type I and osteocalcin), and bone regeneration were performed.

3-dimensional nonwoven chitosan fibrous matrix was developed by fiber bonding technique using acid treatment. The matrix was the effective system of controlled PDGF-BB and in surface modified film, bioactive materials played more significant role in mediating early adhesion or proliferation of progenitor cells promoting tissue engineering. Chitosan fibrous matrix demonstrated good cellular compatibility and bone regenerative potential.

[PE1-24] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Studies on Excipients for oral dosage forms of currently marketed drug products

Kang ShinJung, Yun MiOk, Choi HyunCeol, Kim HoJeong, Park SangAeh^o, Kim JiSun, Kim TaeHee

Korea Food and Drug Administration

Excipients of the drug products can sometimes affect the rate and extent of drug absorption. The changes in components or composition of them can also affect the pharmacological activity. So the quantity of excipients to be changed, the new excipients and atypically large amount of commonly used excipients should be considered as bioequivalence studies. So it is required to review and update excipients presenting in approved drug products. This study reviews formulations in about 2500 drug products of oral dosage forms and sorts excipients of them first by the purpose for formulation and specifies the potency range by the minimum and maximum amounts and percentage to the total weight of them. This study shows usages and amounts of the excipients for currently marketed drug products.

[PE1-25] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

TGF- β 1 Releasing Chitosan Microgranules for Bone Regeneration

Lee Jue Yeon^o Lee Sun Yoon Han Sang Mun Lee Yong Moo Rhyu In Chul Chung Chong Pyoung, Lee Seung Jin

Department of Pharmacy, College of Pharmacy, Ewha Womans University, Seoul, Korea

For the purpose of obtaining high bone forming efficacy, chitosan microgranules were developed as bone substitutes. Chitosan has been applied to conduct the extracellular matrix (ECM) formation in tissue regenerative therapy. Microgranules designed in this study confer drug releasing capacity in bone defect over long period to enhance bone regeneration. Controlled release of TGF- β 1 from chitosan microgranules as bone substitutes may be highly beneficial to enhance bone regeneration.

The morphology of chitosan microgranules, release experiments of TGF- β 1, cell attachment test, bone formation in rabbit calvarial defect site (8mm in diameter) were performed. Steady release of TGF- β 1 was observed after initial burst effect from chitosan microgranules. Initial burst was 40% of loading amount (100ng) and released steadily at a rate of 2-3ng/day. After 7 days incubation, osteoblasts showed extended polygonal morphology and had begun to form an interconnecting network across the surface of the microgranules. Chitosan microgranules treated defects revealed osseous regeneration at 4 weeks compared with non-treated group. New bone

formation was initiated from the periphery to the center of the defect and no adverse inflammatory reaction was observed. These microgranules also have potential as drug delivery systems to accelerate bone healing and cell proliferation.

Poster Presentations – Field E2. Pharmacokinetics

[PE2-1] [04/18/2003 (Fri) 09:30 – 12:30 / Hall P]

Bioavailability of tolperisone in human plasma using a simple HPLC.

Jeong Ji Hoon^o, Park Joon Hong, Choi Tae Sik, Lee Dong Kyu, Jung Chan Heon, Son Byung Hyuk, Sohn Uy Dong

Department of Pharmacology, College of Pharmacy, Chung-Ang University

We aimed at determining bioavailability of tolperisone, a muscle relaxant, and developing a simple analysis in human blood using HPLC. A rapid and sensitive HPLC method was developed and validated using reverse-phase C18 column with retention time and limit of quantification of tolperisone being 7.3 min and 20 ng/ml, respectively. Quantification was performed at 260 nm with chlorphenesin as internal standard. The method involved a simple extraction. In order to study blood level profile in time, eight volunteers were enrolled and orally took 450 mg tolperisone once. The blood sample were collected from 0 to 9 h after the drug administration. Mean AUC and C_{max} value were 556.31±359.2473 (ng/ml·hr) and 353.96±163.5683 (ng/ml), respectively. And Mean T_{max} and T_{1/2} value were 0.94±0.42 (hr) and 1.14±0.27 (hr). From the results we determine the bioavailability of tolperisone using a newly developed and useful HPLC method.

[PE2-2] [04/18/2003 (Fri) 09:30 – 12:30 / Hall P]

A Simple and Rapid Determination of Theophylline in Human Serum by High-Performance Liquid Chromatography and its Application to Pharmacokinetics of Theophylline in Volunteers

Park YoungJin, Kim HyeJung^o, Shim ChangKoo¹, Kwon OhSeung

Toxicology Lab., Korea Institute of Science and Technology, Seoul 136-791, ¹College of Pharmacy, Seoul National University, Seoul 151-742

A simple and rapid method for the determination of theophylline (THP) in human serum was developed by a high performance liquid chromatography/UV detector and applied to pharmacokinetic study of THP in human volunteers. β -Hydroxyethyltheophylline as internal standard was added to 200 μ l of human serum and the mixture was centrifuged at 13000 rpm for 10 min. The supernatant was transferred to Ultrafree-MC centrifugal filter units (0.22 μ m) and centrifuged at 1500 rpm for 3 min. 10 μ l of the filtrate was injected to the HPLC system. Kromasil C₁₈ (4.6 mm x 150 mm, 5 μ m) column and acetonitrile/10 mM acetate buffer (8: 92, v/v%) as