particulates which was effective for obtaining optimal GBR efficacy.
The cellular growth and survival with PLLA particulates against osteoblasts showed 80-110% cellular activity indicating that the particulate system has no significant toxic effect.
Microscopic examination of samples developed with Masson - trichome stain revealed histology patterns for the particulates treated groups. No adverse cellular reac tion including macrophages or multinucleated giant cells was observed.The newly formed bone was observed at the margin of the defect and along the side of dura mater. long-term release of tetracycline from the PLLA particulates enhanced new bone
formation.
Tetracycline released from PLLA particulates enhanced the early bone healing and regeneration.
Tetracycline loaded biodegradable PLLA particulates functioned as a proper long term drug delivery device for guided bone regeneration.

[PE1-22] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Evaluation on the stability of Vitamin preparations- Vitamin A

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Accelerated stability testing was performed on the different 7 dosage forms in order to evaluate the influences of the existence of other vitamins, minerals, excipients on the chemical stability of vitamin A in complicated vitamin drug products. The stability results suggested that increasing of storage time and temperature has resulted in increasing the rate of vitamin A decomposition and the shelf lives(t_{90}) under the test decreased as the storage temperature increased. Vitamin A content was analyzed by HPLC and method validated. All the data were treated as first order kinetics and determined their shelf lives(t_{90}) using Arrhenius plots. The results from Arrhenius plotting were 15.6, 31.0, 17.3 and 43.1, 26.2, 43.0, 21.8, 11.5 months for injection, hard capsule, chewable tablets, ointment, film coated tablet, powder, soft capsule of vitamin A at 25℃, respectively. Injection and ointment of vitamin A were very stable under thermal cycling test. The photostability of vitamin A preparations performed by ICH guidelines was showed vitamin A on the hard capsule, soft capsule and film coated tablet were stable. Though vitamin A on the injection, chewable tablets, ointment and powder were unstable in open containers, they were very stable in final packaging material for marketing. Our results would be helpful to evaluate the stability of multivitamin drug products and be applicable to quality control for vitamin preparations in pharmaceuticals.

[PE1-23] [04/18/2003 (Fri) 09:30 - 12:30 / Hall P]

Nonwoven chitosan fibrous matrix with bioactive agents modified surface and drug release function as tissue engineering scaffold

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For polymeric material for tissue engineering, chitosan was selected with benefit of high tissue compatibility attributed and wound healing through its activation of growth factors. And nonwoven chitosan fibrous matrix has well interconnected porosity. But chitosan itself has some of limitations in inducing rapid bone regeneration at initial states incorpor-ated of bioactive materials such as growth factors and ECM molecules.
Chitosan fibers were prepared by extruding 4% chitosan solution 4% acetic acid into basic

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 matrixdemonstrated 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

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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-β1 Releasing Chitosan Microgranules for Bone Regeneration

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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-β1 from chitosan microgranules as bone substitutes may be highly beneficial to enhance bone regeneration.
The morphology of chitosan microgranules, release experiments of TGF-β1, cell attachment test, bone formation in rabbit calvarial defect site (8mm in diameter) were performed. Steady release of TGF-β1 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