

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 reaction 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**

Kim MiJeong<sup>o</sup>, Chang SungJae, Choi DonWoong, Kim HeeSung, Chang SooHyun, Jung KiSook, Kim JiHa, Choi JongWon<sup>1</sup>, Chang SeungYeup

Korea Food and Drug Administration, 1.Kyungsung University

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°C, 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**

Shim InKyong<sup>o</sup>, Hwang JeongHyo, Yook YeoJoo, Chung ChongPyoung, Lee SeungJin

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

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 incorporated of bioactive materials such as growth factors and ECM molecules.

Chitosan fibers were prepared by extruding 4% chitosan solution 4% acetic acid into basic