ELEVENTH ANNUAL CONFERENCE

YUCOMAT 2009

Hotel “Plaža”, Herceg Novi, Montenegro, August 31 - September 4, 2009
http://www.mrs-serbia.org.rs

Programme
and
The Book of Abstracts

Organised by:
Materials Research Society of Serbia,
and
Institute of Technical Sciences of the Serbian Academy of Sciences and Arts, Belgrade

under the auspices of
Federation of European Material Societies
and
Materials Research Society

Title: THE ELEVENTH ANNUAL CONFERENCE
"YUCOMAT 2009"
Programme and The Book of Abstracts

Publisher: Institute of Technical Sciences of the Serbian Academy of Sciences & Arts
Knez Mihailova 35/IV; P.O. Box 377, 11000 Belgrade, Serbia
Phone: +381 11 2185-437; Fax: + 381 11 2185-263
http://www.itn.sanu.ac.rs

Editor: Prof. Dr. Dragan P. Uskoković

Technical editor: Aleksandra Stojičić

Cover page: Aleksandra Stojičić and Milica Ševkušić

Acknowledgment:

FEMS MRS Materials Research Society

endorsed by biomat.net

nanopaprika.eu

Printed in: Printing office "Čigoja"
Studentski trg 15, 11000 Belgrade
Phones: + 381 11 2186-725; + 381 11 625-954
Circulation: 300 copies. The end of printing: July 2009.

ISBN 978-86-80321-18-9

9 788680 321189

CIP – Каталогизација у публикацији
Народна библиотека Србије, Београд

66.017/.018(048)

MATERIALS Research Society (Beograd). Conference (11 ; 2009 ; Herceg Novi)
Programme ; and The Book of Abstracts / Eleventh Annual Conference YUCOMAT 2009, organized by Materials Research Society of Serbia and Institute of Technical Sciences of the Serbian Academy of Sciences and Arts, Belgrade ; [editor Dragan P. Uskoković]. – Belgrade : Institute of Technical Sciences of SASA, 2009 (Belgrade : Čigoja).– L, 219 str. ; 24 cm

Tiraž 300. – Registar.

ISBN 978–86–80321–18–9
1. Materials Research Society (Beograd) 2. Institute of Technical Sciences of SASA (Beograd)

a) Наука о материјалима – Апстракти b) Технички материјали – Апстракти
COBISS.SR–ID 168339724

O.S.E.3.

IN VITRO AND *IN VIVO* PERFORMANCE OF NANOSIZED HYDROXYAPATITE PARTICLES COATED WITH POLY-DL-LACTIDE-CO-GLYCOLIDE AS SYSTEMS FOR DRUG DELIVERY OF TIGECYCLINE

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Calcium-phosphate/poly(dl-lactide-co-glycolide) (CP/PLGA) composite biomaterial in granular form showed a high potential in the reconstruction of bone tissue. Compared to pure polymers, the combination of CP with biodegradable polymers used in bone drug delivery systems shows certain advantages. Composite biomaterials in nano particulate (NPs) form may have significant advantages over those in micro- or submicro-particulate form.

The purpose of the study presented in this paper has been to examine the possibility of the synthesis of a new nanoparticulate system for controlled and systemic drug delivery with double effect. In the first step, a drug is released from bioresorbable polymer; in the second stage, after resorption of the polymer, non-bioresorbable calcium phosphate remains the chief part of the particle and takes the role of a filler, filling a bone defect. The obtained tigecycline-loaded calcium-phosphate(CP)/poly(dl-lactide-co-glycolide)(PLGA) nano particles contain calcium phosphate coated with bioresorbable polymer and 0.6, 2 and 5wt% tigecycline.

The composite was analyzed by FT-IR, XRD, HPLC and AFM methods. The average particle size of the nanocomposite increases with the augmentation of the part of antibiotics, and it ranges from 65 to 95 nm. Release profiles of tigecycline were obtained by UV-VIS spectroscopy in physiological solution at 37^{o}C. Experimental results were analyzed using Peppas and Weibull mathematical models. Based on kinetic parameters, tigecycline release was defined as non-Fickian transport. The *in vitro* cytotoxicity of the nanocomposite was examined on standard cell lines of MC3T3-E1, in vitro. The obtained low values of LDH activity (under 37%) indicate low cytotoxicity level. Inhibition of bacteria in aerobic and anaerobic conditions *in vitro* was analyzed after 1, 2 and 3 weeks. The behaviour of the composite under real-life conditions was analyzed through implantation of the nanocomposite into living organisms, *in vivo*. The system with the lowest tigecycline content proved to be an adequate system for local and controlled release.