

Regulatory framework and market access of generic medicines in the European Union

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Generic medicines have become essential contributors for government in their effort to contain public health care budgets. Generic medicines are substitutes for originator medicines with the same quality, safety and efficacy. Prices of generic medicines tend to be 10-80% lower than those of innovator medicines so any delay constitutes a missed opportunity for savings to health care budgets and for access to health care for patients. They can enter the market when all protection on the originator medicine has expired which are protected by patents and exclusivity to reward the inventor for dissemination of the details of their invention. In addition to patents, market protection can be extended for other reasons such as supplementary protection certificates, data and marketing exclusivity. The reasons for delay of market access for generic medicines in Europe are their regulatory frame work, pricing and reimbursement of pharmaceuticals. The establishment of a unitary European Union patent together with a unified and specialized patent litigation system, the reduction of backlogs in national agencies, avoiding third party interventions as much as possible and automatic approval of pricing and reimbursement status upon marketing authorization approval of the generic medicines are few polices which would enhance market access of generic medicines in the EU.

Biography

M.Alekya has completed her B. Pharmacy from St. Ann's College of Pharmacy, Vizianagaram and v M.Sc. Regulatory Affairs from Manipal College of Pharmacy, Manipal University, Karnataka. She did poster presentations in several college competition including IPC.

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Fabrication of self-assembled layer-by-layer microcapsules for encapsulation of model charged hydrophilic molecule

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The objective of the present study is to investigate the influence of different encapsulation parameters on entrapment of a model hydrophilic molecule, ascorbic acid into self-assembled layer-by-layer (LbL) microcapsules.

Layer-by-layer assembly of oppositely charged polyelectrolytes poly (sodium-4-styrene sulfonic acid) (PSS) and poly (ethyleneimine) (PEI) onto sacrificial calcium carbonate particles have yielded hollow microspheres. The LbL assembly of resultant microcapsules after six bilayers was characterized using optical microscopy, scanning electron microscope (SEM), differential scanning calorimeter (DSC) and Fourier-transform infrared spectroscopy (FT-IR). Influence of incubation time, drug concentration, pH and ionic strength on entrapment of ascorbic acid into microcapsules was investigated.

Microscopic results show that calcium carbonate microspheres and LbL microcapsules were spherical in shape, with particle size of $1.4 \pm 0.5 \mu\text{m}$ and $2.4 \pm 0.1 \mu\text{m}$ respectively. FT-IR studies showed proportional increase in area of PSS and PEI peaks in prepared microcapsules. DSC thermograms showed interaction of polymers in microcapsules with shift in T_g and T_m of polymers. Two hours of incubation of microcapsules with drug showed loading of $14.01 \pm 3.8\%$. Encapsulation up to $27.03 \pm 4.75\%$ was seen with increase in pH from 4 to 10. Increase in salt concentration showed increase in encapsulation from $27.03 \pm 4.75\%$ to $40.25 \pm 2.79\%$. Highest encapsulation of $41.11 \pm 3.24\%$ was observed with the drug concentration of 5mg/ml. In vitro release from the microcapsules was measured and compared with ascorbic acid solution. Microcapsules are showing sustained release over a period of 48 hours in comparison to bare drug molecules.

Our studies showed that self-assembled LbL microcapsules can be developed as carriers for controlled delivery of charged hydrophilic molecules.

Biography

Manali P Koranglekar is currently pursuing her master's degree with specialization in pharmaceuticals from BITS Pilani Hyderabad campus. She has been working for the project titled "Fabrication of self-assembled layer-by-layer microcapsules for encapsulation of model charged hydrophilic molecule" under the guidance of Dr.V.V Vamsi Krishna since last 10 months. Dr.V.V Vamsi Krishna has completed his PhD from The South Dakota State University and currently is the head of department, Pharmacy, in BITS Pilani Hyderabad campus.

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