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Design and selection of suitable niosomal formulation of finasteride by using different non-ionic surfactants

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Nowadays the challenge is incorporating an existing medicine into a new drug delivery system can significantly improve its performance in terms of efficacy, safety, and improved patient compliance. The need for delivering drugs to patients efficiently and with fewer side effects has prompted researchers to engage in the development of new drug delivery systems. Development of novel drug delivery systems (NDDS) for variety of drugs is very important in order to increase the drug targeting and effectiveness. This can be done by developing one of NDDS i.e. Niosomal system which is vesicular drug delivery system. In the present work, Niosomal system of Finasteride was prepared by the incorporation of various classes of non ionic surfactants (Span 20, Span 80, Tween 20, Tween 80 and Brij35), cholesterol and the drug finasteride. Niosomes were prepared by using lipid film hydration technique. Different formulations of finasteride were prepared and named as F1, F2, F3, F4 and F5. The prepared formulations were subjected for entrapment efficiency, vesicular size for the selection of suitable formulation for further studies. Among the formulations, F1 showed better results as compared with other formulations of Finasteride F2, F3, F4 and F5. The optimized formulation of Finasteride F1 was used for further studies.

Keywords: Novel drug delivery system, Vesicular drug delivery system, Niosomes, Finasteride, Entrapment efficiency.

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Regulatory challenges involved in development and commercialization of bisimilars

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The term Biosimilars is used to describe officially-approved subsequent versions of innovator biopharmaceutical products made by a different sponsor after the expiry of patent on the innovator product. Biosimilars differ from generic drugs because their active ingredients are huge molecules with intricate structures like recombinant Protiens, Aminoacids, Hormones, vaccines etc. Such molecules are nearly impossible to replicate in every detail - even in the hands of the original manufacturer. Unlike the relatively simple construction of a conventional small-molecule drug. Coming to the approval of Biosimilars, should consider lot many issues which are much more complicated than the approval of generic equivalents of conventional pharmaceuticals. Thus, verification of the similarity to Biosimilars with reference innovator biopharmaceutical products will require much more than a demonstration of pharmacokinetic similarity. Regulatory requirements for the approval of Biosimilars have not yet been fully established, but preliminary guidelines from the European Agency for the Evaluation of Medicinal Products (EMEA) state that the complexity of the product, the types of changes in the manufacturing process, and differences in quality, safety and efficacy must be taken into account when evaluating Biosimilars. For most products, results of clinical trials demonstrating safety and efficacy are likely to be required. In addition, because of the unpredictability of the onset and incidence of immunogenicity, extended post-marketing surveillance is also important and may be required. The aim of this work is to provide a brief overview of the regulatory challenges faced in developing and commercialization of Biosimilars.

Biography

M.N. Raviteja is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. He has completed his B Pharm from JSS College of Pharmacy, Mysore during the year 2012. Presently he is pursuing M Pharm in Pharmaceutical Quality Assurance in JSS College of Pharmacy, Mysore. He has presented posters at national level and has attended various National and International Conferences. His current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, GMP Auditing.

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