Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.008

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

Regulatory Compliances in Health Care

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The regulation of new drugs in United States is based on NDA (New Drug Application).Its mission is to ensure that patients get access to good medicines without unnecessary delay,help pharmaceutical companies to get their medicines to the market at the right time, help regulatory agencies to approve the right medicines much faster. .NDA provides information to FDA (Food and Drug Adminstration) reviewers if the drug is safe and effective,the benefits of the drug outweighs the risks,drugs proposed labelling is appropriate,the methods and controls used in manufacturing drug to maintain drugs quality are adequate to preserve its identity,strength,quality and purity.Documentation also demands drugs whole story,what happened during clinical trials,how drug behaves in the body,how it is manufactured,processed and packaged.ANDA (Abbreviated New Drug Application) do not require preclinical (animal) and clinical (human) studies to establish safety and effectiveness.It should scientifically demonstrate that their product is pharmaceutically equivalent bio-equivalent with the innovator drug and thus fully interchangeable with the innovator drug.Once approved the applicant can manufacture and market the generic product as safe,effective and low cost alternative.The generic version must deliver the same amount of active ingredients into a patients blood stream in the same time as the innovator drug.

Biography

I am presently doing my post graduation(M.Pharm) in the branch of Pharmaceuical Analysis and Quality Assurance at Andhra University College of Pharmaceutical Sciences.Did my graduation(B.Pharm) at Shri Venkateswara College of Pharmacy, Etcherla.

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Cyclodextrin based carbonate nanosponges for complexation of paliperidone

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Paliperidone a potent antipsychotic agent has a limited therapeutic utility because of poor aqueous solubility, gastric instability and serious side effect which have been related to high blood plasma concentration, thus restrict the administration of single daily immediate release dose. Cyclodextrin based nanosponges are novel class of cross linked cyclodextrins by using cross-linking agents like carbonate, ester etc; and used to increase solubility of BCS class II and IV drugs etc. This study aimed to form complex of Paliperidone with cyclodextrin based nanosponges to increase water solubility and gastric acid stability. Plain Paliperidone and paliperidone nanosponges (PPNS) were compared for selected pre formulation parameter and release rate of drug from nanosponges was determined. Nanosponges with different molar ratio of β-Cyclodextrin(CyD):Diphenyl carbonate (1:2, 1:4, 1:8) were synthesized and 1:4 was selected to complex Paliperidone on the basis of percent yield (%Y) and PS; after G3 morphology nanosponges. Stability study of nanosponges was ascertained by subjecting sample double moist heat sterilization and Dynamic vapor sorption. Freeze drying was used for paliperidone loading. Formed NS; and PPNS interaction were confirmed by FTIR, DSC, and XRPD. Solubility of PPNS and of CyD-paliperidone physical mixture was determined (by UV-spectrophotometer). Stability of paliperidone in SGF as such and as PPNS was determined and drug contain measured. In vitro drug release was determined by multi compartment rotating cell. %Y of nanosponges 1:4 was found to be 55%. PS of nanosponges and complex were below 800 nm and 750 nm respectively. XRD pattern confirmed that non hygroscopicity of nanosponges and interaction of PPNS (by decrease in drug crystallinity). G3 morphology study showed particles were somewhat spherical in nature. Gastric stability of paliperidone was found to more as PPNS. In vitro release rate showed 24 % drug release in 2hr. The research work reported here form basis for consideration of CyD based carbonate nanosponges for Paliperidone delivery. Further studies including in vitro, in vivo permeation, toxicity, biopharmaceutics etc. need to be performed to defined rout of administration and suggest suitable dosage form.

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