

Formulation and evaluation of niosomes of eletriptan hydrobromide for nasal drug delivery system

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Eletriptan hydrobromide is a potent anti-migraine drug. The purpose for the present investigation is to formulate and evaluate proniosomal nasal drug delivery system of eletriptan hydro bromide using coacervation phase separation method. Proniosomes are prepared using various non-ionic surfactants like span 80, tween 80 and combination of both span and tween with or without cholesterol from 0 to 50%. the effect of non-ionic surfactant and cholesterol was identified. The drug release from the prepared system was carried out and was compared with eletriptan hydrobromide tablets (Relpax tablets). Further the niosomes prepared where also tested for entrapment efficiency, rate of hydration, vesicle size and in-vitro analysis. The entrapment efficiency was found to be 47.9+0.96%. The niosomes released 58.91% eletriptan hydrobromide over a period of 5h and 78.1% of the drug was absorbed from the nasal mucosa.

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Good Manufacturing Practice a regulatory aspect

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The observance of Regulatory direction is an essential pre-requisite of GMP. The Pharmaceutical products are to be manufactured only by the licensed manufacturers, whose activities are regularly monitored by the competent regulatory authorities within and Exporting nations. Regulation is vital to ensure that the drugs are as effective as they claim and pose no unknown dangers to the Public. GMP guidelines are available and basic concepts of these guidelines are safeguarding the health of patients and producing good quality medicines. Quality, safety and efficacy are designed and built into product right from development stage and throughout the product's life style. Well built quality systems will facilitate improvement in product, process and quality enhancements to reduce the recalls and defective product entering market. GMP specifies each process and systems are to be validated and then ensured through in process controls and analysis of final product before release. Each step of manufacturing process is controlled to assure that the finished product meets all design characteristic and quality attributes including specification. Quality cannot be adequately assured merely by inprocess and final product testing. Regulatory compliance is assured by establishing documentary evidence to prove systems performs according to specifications and these performances are consistent and reproducible. Regulatory, expects that the production processes are understood well and to track the processes in real time using things like control charts and process capability to make sure that nothing changes.

Biography

S N Kilikar has completed his graduation in Chemistry from Kerala University, India in the year 1973. He is having an experience in Pharmaceutical Industry for more than 37 years in the field of QC, PRODUCTION and GMP Implementation including Validation. Now he is working as a consultant to support Pharmaceutical units to develop new Facilities, Documentation, Validations and other cGMP requirements. He is conducting many Training programmes including for sterile manufacturing. Technical audits are conducted to rectify and upgrade the systems to cGMP level. Three AYURVEDA manufacturing units are set up in Kerala conforming to cGMP standards.

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