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## Regulatory affairs of medical devices

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Medical devices in addition to medicines and other health technologies are essential for patient care, are currently one of the fastest growing industries.They contribute a lot to the global market with the advancement of innovation and technology. WHO is reinforcing its role in providing technical support to its member states to protect their populations from risks of unsafe technology.So,regulatory contrrol is needed over medical devices to prevent the use and importation of substandard devices. Global Harmonisation Task Force's (GHTF) mission is to harmonize the implementation of medical device regulation across the globe,to encourage convergence in standards and regulatory practices facilitating international trade.Different national and international standards were formulated and set for each country to see that materials,process,products are fit for their purpose. Safety and performance of the medical device is monitored for regulation in different phases in the life cycle of a medical device from development to the disposal of the device.Stages in regulatory control involve pre- market,placing on market and post market approval/vigilance to ensure that device meets all its specifications.This is because every device carrries a certain degree of risk and potential problems can never be detected until extensive market experience is gained.They are classified into caegories based on the potential risk they pose.The role of regulatory authority is to ensure that manufacturer has fulfilled all the regulatory requirements.

### Biography

Currently pursuing my post graduation (M.Pharm)at Andhra University in the branch of Pharmaceutical Analysis and Quality Assurance.Did my graduation(B.Pharm) from Shri Vishnu College of Pharmacy,Bhimavaram.

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## Feasability study of matrix tablet for gastroretention application

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The objective of this study was to formulate and evaluate matrix tablets for controlled delivery of dextromethorphan hydrobromide (DBM) as a model drug. Matrix tablets were prepared by direct compression method using tamarind seed polysaccharide (TSP) as release retardant material and HPMC K15M and K100M as swelling agents. Prepared matrix tablets were characterised by FT-IR and DSC. FT-IR and DSC studies showed no chemical interaction between the drug and polymers. Matrix tablets were optimized on the bases of acceptable tablet properties like hardness, friability, drug content, weight variation, buoyancy percentage, in vitro and in vivo floatation in rabbits. Among all the formulations, F-IV showed 99.2% release at the end of 12 hours. The release data was fitted to various mathematical models such as, Higuchi, Korsmeyer-Peppas, First-order and Zero order to evaluate the release kinetics and mechanism of drug release followed fickian diffusion mechanism. The in vivo floatation study confirmed that floating matrix tablets could prolong the gastric retention time to more than 12 hours. Results of the stability studies showed that there were no significant changes in the drug content and physical appearance.

### Biography

K. Ajith Reddy is a student of JSS College of Pharmacy, JSS University, Mysore, Karnataka, India. He has completed his B.Pharm from JSS College of Pharmacy, during the year 2011. Presently he is pursuing M.Pharm in Industrial Pharmacy group, Department of Pharmaceutics. His present interests are in Nanoparticles and Novel Drug Delivery Systems.

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