

2nd International Conference and Exhibition on **Pharmaceutical Regulatory Affairs**

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

Effect of surfactant on dissolution profile of poorly water soluble acidic drugs

Pankaj A. Cheke

Shivaii university. India

The effects of types of surfactants on the solubilization and dissolution of poorly soluble acidic drugs were compared to identify the most suitable surfactant for conducting an acidic drug dissolution test, sodium lauryl sulfate (SLS) as an anionic surfactant, and polysorbate 80 as a non-ionic surfactant were used in the study. And nimesulide, were selected as model drugs. The dissolution rates of these acidic drugs were substantially enhanced in medium containing Electrostatic interactions between acidic drugs and anionic surfactants were confirmed by measuring UV spectra of each drug. Solubility of drugs in various media and the partition coefficients of drugs into micelles were found to depend on drug characteristics. For acidic drugs, the ability of media containing a cationic surfactant to discriminate rates of dissolution of acidic drugs seemed to be greater than that of media containing other surfactant types.

Biography

Mr. Pankaj A. Cheke, doing M.Pharm(Pharmaceutics) in Shivaji University, Kolhapur. Presented posters in various national and international conferences.

pacheke.tkcp@gmail.com

Challenging framework of controlled drugs in India: A regulatory perspective

Pooja M. B

JSS University, India

Impossibilities are merely things which we have not yet learned". So even with the challenges related to the approval of controlled drugs (Narcotics and Psychotropic drugs) in India in terms of stringent laws, multiple regulations and parallel approvals the demand is immense for only reason of "Benefits far outweigh the risk". Pain is one of the most dreaded side effects of cancer where 1 in 3 patients suffer from sever acute and chronic cancer pain. Patients with austere pain are usually treated with an opioid drug, which has been the gold standard to treat or prevent anticipated episode of pain. Need of regulatory standards regarding the efficacy, safety and abuse potential nature makes it more challenging in India with multiple approvals required for its research study, marketing and surveillance. The regulations demand a multiple submissions for approval to CBN (Central Bureau of Narcotics), CDSCO (Central Drugs Standard Control Organisation) and Ethical committee for both clinical trial and marketing authorisation in India. The situation is changing now, and there is an increasing body of literature, related side effects, interactions, challenges and opportunities which pave both regulatory and market perspective for launching controlled drug in Market. The need of the hour is for all Pharma stake holders to unite on a single platform to lobby with central and state government agencies for seeking solutions to simplify the regulatory procedures for clinical research, MAA, and PMS by protecting the interest of Indian patient and preventing misuse.

Biography

Pooja M. B has completed her B. Pharm and is currently pursuing her final year M. Pharm in Pharmaceutical Regulatory Affairs under JSS University in JSS College of Pharmacy Mysore Karnataka. She is a gold medalist in her final year B. Pharm and stood second in her first M. Pharm for the University. She has attended many national and international conferences and workshops where she has presented many posters. She has published many articles in reputed journals.

pooja_balachandra@ymail.com