EXECUTIVE SUMMARY OF UGC MINOR RESEARCH PROJECT

GRANT DETAILS

F. No.:**47-865/13 (WRO) dated 28 Jan 2015**

Title: **Development and pharmacokinetic study of travellers friendly oral thin film of poorly soluble drug**

Name of Principal Investigator: **Mr GALGATTE U C**

Duration:**2015-2017 (Two Years)**

College:**P E Society's Modern College of Pharmacy, Nigdi, Pune 411044**

Effective date of starting the project:**11 Feb 2015**

SUMMARY OF THE RESEARCH PROJECT

The development of orodispersible films (ODF) containing dimenhydrinate (DMH) offers an alternative to conventional tablets, syrups and suppositories for the treatment of vomiting and nausea. Chemically, DMH is a salt of diphenhydramine and 8-chlorotheophylline. Diphenhydramine is an antihistamic drug that is antagonistic at the H1 receptor in order to prevent and treat nausea and motion sickness. However the compound undergoes moderate first pass metabolism, which limit the bioavailability to 40%. The aim of the present study was to design the fast dissolving oral film of dimenhydrinate by solvent casting method using pectin LM as film forming polymer. The casting was carried out by using film former. The polymer, pectin LM could be moulded by hydration towards its film forming property. The formulation batches were optimized by 3^2factorial design.

FT-IR studies revealed that there is no chemical interaction between dimenhydrinate and pectin LM used in the study. The DSC thermogram showed clear peaks at their melting point. PXRD of pure dimenhydrinate, pure pectin and optimized formulation of film indicate crystalline nature of drug. SEM study revealed the rough and porous surface of film.

Formulation and optimization of films were done which gives satisfactory results for various physio-chemical evaluation of films like physical appearance, mechanical propertiessuch as tensile strength, percent elongation (16.35±3.75%), folding endurance (77±3.01%)etc and pH of film (6.1±0.90), in vitro disintegration time(45± 1.20 seconds), drug content (97.78±1.85%), in-

vitro drug release (94±2.01%). Based on the characterization and evaluation of films, the batch F5 was found optimum among all factorial batches. Accelerated stability studies shown that samples became hygroscopic in nature during stability. Some process variables were studied such as drying temperature, distance between dragger and surface of film former and hydration conditions of pectin LM. The effect of drying temperature was found significant. Temperature 72 degrees to 80 degrees wereaffecting much on quality of film. Besides the objectives of the project work the utility of pectin LM as film forming polymer is improved. The fast dissolving oral film of dimenhydrinate now becomes choice for delivery of dimenhydrinate for pediatric population while travelling. The compliance of this film would be better by pediatric population in case of emesis while travelling. This would be the substitute dosage form of dimenhydrinate tablets and oral liquids for pediatric population.

Galgatte U C

Principal Investigator