TITLE: FORMULATION, EVALUATION AND CHARACTERIZATION OF FLUOXETINE ORODISPERSIBLE FILMS USING DESIGN OF EXPERIMENT.

Kalpita S. Nadkar[1], Dr.Antoine J. Al-Achi[2]

[1]Master of Science student at Campbell University, NC, USA

[2]Professor of Pharmaceutics and Biomedical Sciences
Track Head/Industrial Pharmacy (Master of Science in Pharmaceutical Sciences)
Campbell University, NC,USA

ABSTRACT

Depression is a major worldwide concern as per WHO fact sheet that emphasizes the fact that about 300 million people are victims of depression leading to an alarming number of about 800000 suicides every year. Current antidepressants take time to work as they have to be taken orally, followed by first-pass metabolism to actual therapeutic effect which can put a severely depressed person's life at stake especially the ones who have suicidal tendencies. Fluoxetine, a Selective Serotonin Reuptake Inhibitor (SSRI) was approved in 1988, is still the most common and preferred prescribed anti-depressant. The Orange book yet, does not have a formulation that delivers this API rapidly. An urgent need arises to formulate this drug as a rapid release dosage form: Orodispersible films. Difficulty in swallowing tablets is experienced by about 26% of patients. Orodispersible films have garnered attention due to its unique formulation that proves suitable for use for dysphagic patients, paralyzed patients, geriatric and pediatric, bedridden, mentally challenged population worldwide. These orodispersible films are paper thin polymeric films that disintegrate or dissolve quickly when placed on the tongue or the oral cavity to release the medicament thus bypassing first-pass metabolism as most of the API gets absorbed via the sublingual mucosa due to the highly permeable physiology coupled with rich blood supply that aid in absorption and distribution of the drug into the systemic circulation leading

to rapid onset of pharmacological actions and fast relief. In this research, optimized Fluoxetine Hydrochloride orodispersible films for sublingual use were formulated using DoE using JMP® Pro 13 using the solvent casting technique. Prior to formulation, the drug excipient compatibility studies were carried using FTIR. The optimized formulae for both the polymers had a disintegration time of 30 seconds or less. These orodispersible films were 15 mm diameter circles each containing Fluoxetine HCl (10mg/film) as the API, Kollicoat IR or HPMC E15 individually as the polymers, Glycerol as plasticizer and Aspartame as the sweetening agent, Green or Yellow food dye as a coloring agent. On the optimized formulation, various evaluation tests like weight variation, thickness of the film, disintegration time, folding endurance, surface pH, Tensile strength, Hydration study, percent moisture loss, percent drug release (time point drug dissolution) were conducted. Characterization studies were carried using slide crystallization, TGA, DSC, PXRD. It was concluded that though challenging, films of Fluoxetine HCl can be prepared.