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RESEARCH ARTICLE

Implementation of Quality by Design approach for Development of Optimized Drug Delivery System of Antidepressant Drug

Vijay Sharma[1], Lalit Singh[2], Arpit Jaiswal[3], Md. Semimul Akhtar[4]
[1]Pharmacy Academy, IFTM University, Moradabad, India.
[2]JPM College of Pharmacy, Bareilly, India.
[3]SRMSCET, Pharmacy, Dept. of Pharmaceutical Technology, India.
*Corresponding Author E-mail: **Lalit4u78@gmail.com**

ABSTRACT:
The work presented aimed to implement of "Quality by Design" (QbD) approach to develop optimized fast dissolving tablet (FDT) of Fluoxentine. A face centered Central composite design was employed to develop optimized dosage form. FDTs were prepared by direct compression followed using sublimation technique with additive effect of super disintegrants. Impact of independent variables such as concentration of super-disintegrant and sublimating agent was determined on dependent variables i.e. wetting time, disintegration time and drug release. Data optimization was done by developing validation check batches as well as overlay plot developed by statistical software. Optimized formulation shows 18.08 s wetting time (WT), 19.84 s disintegration time (DT) and the drug release was found to be 85.82 % in 5 m. The accelerated stability studies for optimized FDTs shows no significant changes during one month stability studies. In conclusion, the optimized fast dissolving tablets for Fluoxentine was successfully developed employing by QbD approach with least utilization of man, money and efforts.

KEYWORDS: Fast Dissolving Tablet, Sodium Starch Glycolate, Camphor.

INTRODUCTION:
Fast dissolving drug delivery system can be defined as the one which disintegrates rapidly in saliva within few seconds without the need of drinking water or chewing when placed on tongue[1]. Despite of tremendous development in drug delivery system, oral route is the most preferred route for drug administration due to following advantages like low cost of therapy, ease of administration, accurate dose, self medication, pain avoidance, versatility and the most importantly patient compliance. Fast dissolving tablet (FDT) has been formulated for pediatric, geriatric and bed ridden patient even for the active person who is busy and travelling which may not have excess of water[2-3]. Tablets and capsules are one of the acceptable dosage forms but the major drawback associated with this dosage forms is dysphasia or difficulty in swallowing.

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This problem led to development of novel solid dosage forms such as FDT that will disintegrate and dissolve rapidly in saliva without need of drinking water.

Fluoxentine Hydrochloride (FH) an antidepressant agent was approved by US Food and Drug Administration (US FDA) in 2011[4]. Through FH is absorbed after oral intake but the bioavailability is 72%[5], as FDT increase the bioavailability by pre gastric absorption of drug from mouth, pharynx and esophagus as saliva passes down in the stomach[6]. Therefore an attempt was made to formulate and optimize FDT by using central composite design (CCD) that shows quicker onset of action[7] by varying the different concentration of camphor (CAM) used as sublimating agent and Sodium starch glycolate (SSG) as super -disintegrant.

MATERIAL:
Fluoxentine HCl was provided as gift sample from Geneka Healthcare, Haidrwar, India. Talcum, Sodium starch glycolate, Magnesium stearate were purchased from Central Drug House, New Delhi, India; Camphor, Sucrose were purchased from Loba Qualigens fine labs,