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FORMULATION AND INVITRO CHARACTERIZATION OF FLUVOXAMINE LOADED NANO PARTICLES

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ABSTRACT

The real challenge in the development of a controlled drug delivery system is not just to control the drug release, also to extend the existence of the dosage form in the absorption site until all the drug is completely released in the preferred period of time. Nanoparticulate carriers may provide a better therapeutic output by targeting drugs specifically to their site of action and by improving the pharmacokinetic profile of effective drugs low bioavailability and low half-life. In present inviuestigation Nanoparticles were prepared by emulsification method. New Nanoparticulate drug carrier that combines the benefits of polymeric nanoparticles to enhance the bioavailability of drugs, retain the drug in the absorption site more than the half-life of the drug, reduce dose frequency, toxicity and patient compliance. Total nine nanoparticles formulations was formulated using Ethyl cellulose, Eudragit RS 100 & Eudragit RL 100. The drug release from the Nanoparticles was explained by the using mathematical model equations such as zero order, first order, and equation methods. Based on the regression values it was concluded that the optimized formulation F6 follows Zero order drug release with super case II transport mechanism.

KEYWORDS: Nanoparticles, Eudragit RS 100, Fluvoxamine, Emulsification, bioavailability, Ethyl cellulose.

INTRODUCTION

Oral drug delivery is the most favoured manner of drug delivery for achieving mutually systemic and local therapeutic effects. But a variety of problems are also related with the conventional oral dosage forms, that it is frequently essential to take several times per day to retain the concentration of administered drug within the therapeutically effective range which results in a fluctuated drug level and consequently undesirable toxicity and poor efficiency. So to overcome such problems associated with conventional oral dosage form, the idea of controlled drug delivery systems was introduced[3].The real challenge in the development of a controlled drug delivery system is not just to control the drug release, also to extend the existence of the dosage form in the absorption site until all the drug is completely released in the preferred period of time.[4-6]

Continuous release of the drug involves polymers that release the drug at a controlled manner due to the degradation of polymer over time and it can be achieved by using drug carrying polymer. In the present work, our aim was to develop a new nanoparticulate drug carrier that combines the benefits of chitosan nanoparticles and cyclodextrins to enhance the bioavailability of drugs, retain the drug in the absorption site more than the half life of the drug, reduce dose frequency, toxicity and patient compliance. The drug is dissolved, entrapped, encapsulated or attached to a nanoparticle matrix. The term nanoparticle is a combined name for both nanosphares and nanocapsules. Drug is confined to a cavity surrounded by a unique polymer membrane called nanocapsules, while nanospheres are matrix systems in which the drug is physically and uniformly dispersed. Where conventional techniques reaches their limits, nanotechnology provides opportunities for the medical applications.[1-2]

METHODOLOGY

Materials: Fluvoxamine from Spectrum labs, Ethyl cellulose from Signet Chemical Corp., Mumbai, Eudragit RS 100, Eudragit RL 100 from sigma Aldrich Mumbai.

Instruments: Digital balance form Essae-Teraoka ltd, DS-852j, UV Spectrophotometer from PG Instruments, T60 FTIR Spectrophotometer from Shimadzu -8400 S and pH meter from Hanna Instruments, Italy.

Pre-formulation studies[7-11]

Prior to the development of dosage form, it is essential that certain fundamental physical and chemical properties of the drug molecule alone and when combined with excipients are determined. This first learning phase is known as pre-formulation. The overall objective of the pre-formulation is to generate information useful to the formulator in developing stable and bioavailable dosage forms which can be mass produced. The goals of pre-formulation studies are:

- To evaluate the drug substance analytically and determine its necessary characteristics
- To establish its compatibility with different excipients.

SPECTROSCOPIC STUDY

Identification of pure drug

Solubility studies

Solubility of Fluvoxamine was carried out in different solvents – like 0.1N HCL, 6.8pH buffer and 7.4 pH buffer. Saturated solutions were prepared by adding excess drug to the vehicles and shaking on the shaker for 48 hr. at 25°C under constant vibration. Filtered samples (1ml) were determined spectrophotometrically at 250 nm.

Drug-Excipient Interactions Studies: There is always possibility of drug- excipient interaction in any formulation due to their intimate contact. The technique employed in this study is IR spectroscopy.

IR spectroscopy is one of the most powerful analytical technique, which offers possibility of chemical identification. The IR spectra was obtained by KBr pellet method. (Perkin-Elmer series 1615 FTIR Spectrometer).

Determination of UV spectrum of Fluvoxamine

10mg of Fluvoxamine was dissolved in 2-3ml of 7.4pH buffer then makeupto10ml with 7.4 pH buffer so as to get a stock solution of 1000 µg/ml concentration. From the above stock solution pipette out 1ml of the solution and makeup the volume to 10ml using 7.4 pH buffer to get the concentration of 100µg/ml concentration. From this stock solution pipette out 1ml of the solution and makeup the volume to 10ml using 7.4 pH buffer to get the concentration of 10µg/ml concentration, this solution was scanned under UV Spectroscopy using 200-400nm.

PREPARATION OF CALIBRATION CURVE OF FLUVOXAMINE

Standard calibration curve of Fluvoxamine using 7.4 pH buffer.

Method: 10 mg drug was taken accurately in 10ml volumetric flask. It was dissolved in few ml of methanol and make up the volume upto the mark with 7.4 pH buffer to gives 1000 µg /ml. The standard stock solution was then serially diluted with 7.4 pH buffer to get 2 to 12 µg/ml of Fluvoxamine. The absorbance was measured against 7.4 pH buffer as blank at 232 nm using UV spectrophotometer. The absorbance values were plotted against concentration (µg/ml) to obtain the standard calibration curve.

Method of Preparation of Nanoparticles[12, 13,14,15,16,17]

Fluvoxamine Nanoparticles were prepared by emulsification method. In this method Polymer was dissolved in organic solvent (methanol). Drug is dispersed in this solution. Then this mixuture emulsified in an aqueous phase containing surfactant (polyvinyl alcohol) make an oil in water emulsion by using mechanical stirring, or sonication. After formation of emulsion the organic solvent evaporate by increased the temperature and reduced pressure with continuous stirring.

Formulation code	Drug:polymer	Ratios	Concentartion of PVA (%w/v)
F1	Drug : Ethyl cellulose	1:1	2
F2	Drug : Ethyl cellulose	1:2	2
F3	Drug : Ethyl cellulose	1:3	2
F4	Drug : Eudragit RS 100	1:1	2
F5	Drug : Eudragit RS 100	1:2	2
F6	Drug : Eudragit RS 100	1:3	2
F7	Drug : Eudragit RL 100	1:1	2
F8	Drug : Eudragit RL 100	1:2	2
F9	Drug : Eudragit RL 100	1:3	2

RESULTS AND DISCUSSION

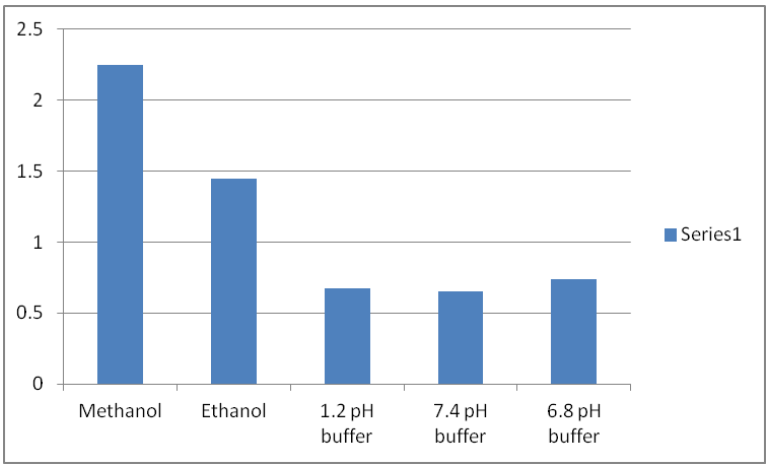
PREFORMULATION STUDIES

SOLUBILITY STUDIES

Saturation solubility was carried out at 25^0C using 0.1N HCL, 6.8 and 7.4 phosphate buffer, ethanol, and methanol.

Table 1: Solubility Studies Data of Fluvoxamine.

Solvent	Solubility (µg/ml)
Methanol	2.25
Ethanol	1.45
1.2 pH buffer	0.676
7.4 pH buffer	0.652
6.8 pH buffer	0.737



DISCUSSION

From the above conducted solubility studies in various solvents we can say that methanol shows highest solubility than other solvents.

Determination of absorption maximum (λmax):

Determination of Fluvoxamine λ-max was done in pH 7.4 buffer medium for accurate quantitative assessment of drug dissolution rate.

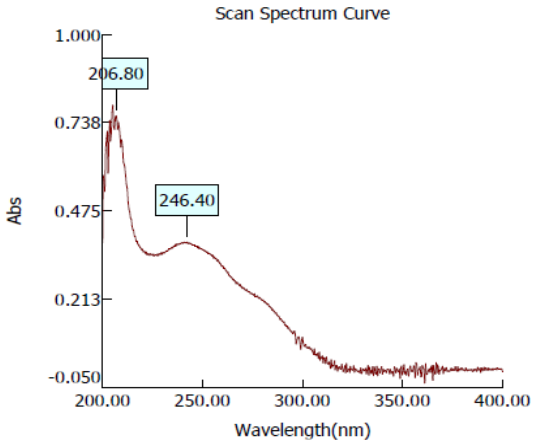


Fig. 1: UV Spectrum of Fluvoxamine.

UV Spectra of Fluvoxamine at 10µg/ml concentration. Wavelength of maximum absorption in 7.4pH buffer was found to be 245nm.

Standard Calibration curve of fluvoxamine:

Table: Calibration curve of fluvoxamine in 7.4 pH buffer.

Concentration (µg/ml)	Absorbance
0	0
2	0.108
4	0.214
6	0.325
8	0.433
10	0.535
12	0.634

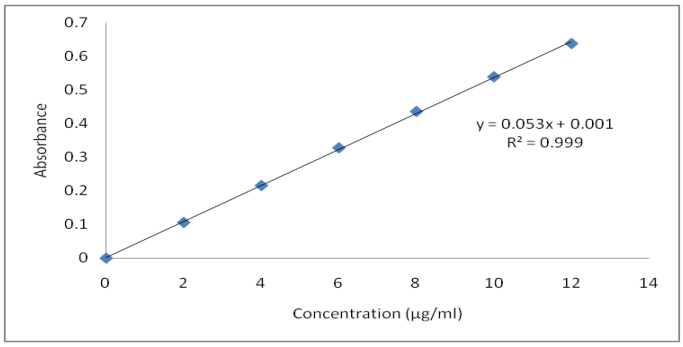


Fig. 2: Calibration curve of fluvoxamine in 7.4 pH buffer.

The linearity was found to be in the range of 2-12 µg/ml in pH 7.4 buffer. The regression value was closer to 1 indicating the method obeyed Beer-lamberts' law.

Drug and Excipients compactability studies

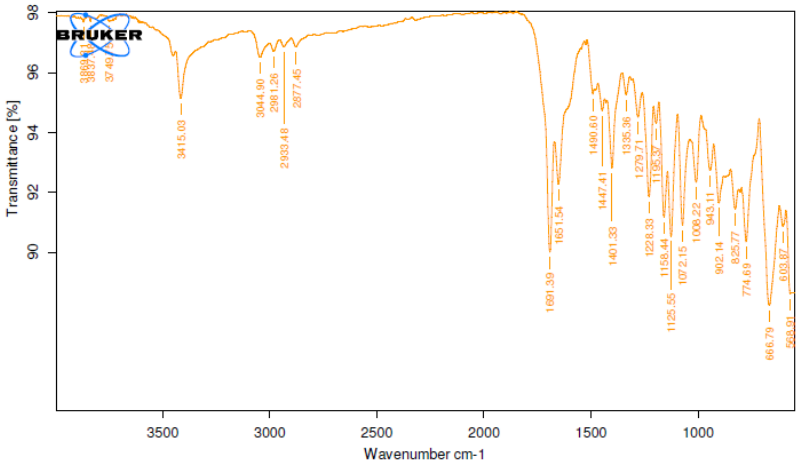
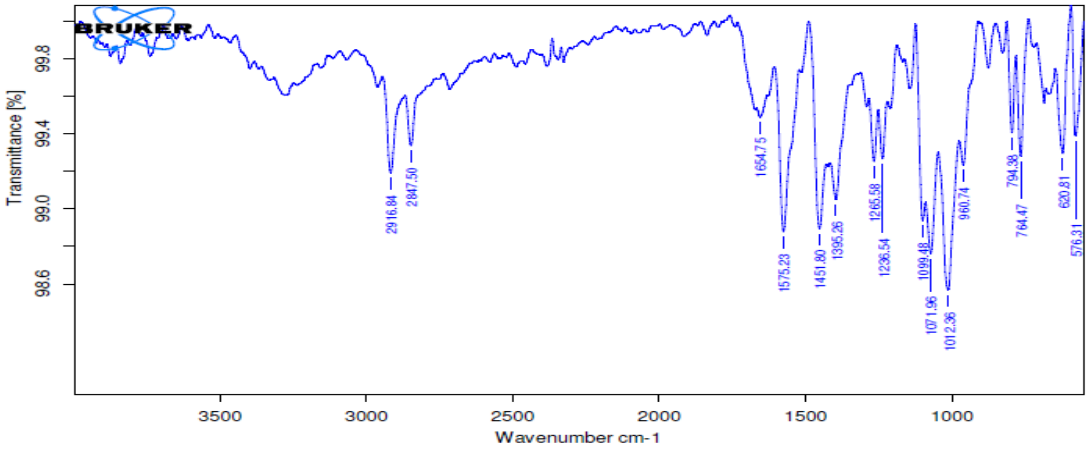


Fig. 3: FTIR of Pure Drug.



CONCLUSION

Estimation of Fluvoxamine was carried out spectrophotometrically at 245nm. The Nanoparticles were evaluated for parameters such as drug content uniformity, scanning electron microscopy, particle size analysis, zeta potential, in-vitro release, Drug release kinetics. Form the drug excipient compatibility studies we observe that there are no interactions between the pure drug (Fluvoxamine) and optimized formulation (Fluvoxamine+ excipients) which indicates there are no physical changes. Zeta potential value for the optimized formulation (F6) was found to be within the acceptable limits. Average particle size of Nanoparticles of optimized formulations (F6) was found to be 180nm. From the invitro studies we can say that formulation F6 shows best drug release of 98.05% within 12 hrs to release the drug. The drug release from the Nanoparticles was explained by the using mathematical model equations such as zero order, first

order, and equation methods. Based on the regression values it was concluded that the optimized formulation F6 follows Zero order drug release with super case II transport mechanism.

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