Available online on www.ijpqa.com
International Journal of Pharmaceutical Quality Assurance, 2(4); 73-75

ISSN: 0975 9506

Research Article

Spectrophotometric Estimation of Fluvoxamine Maleate in Tablets Using Hydrotropic Agent

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ABSTRACT
Several techniques are used to increase the aqueous solubilities of poorly water soluble drugs. Hydrotropic solubilization technique is one of them. In the present investigation hydrotropic solution of Urea (10M) has been used as a solubilizing agent to solubilize poorly water soluble drug. Fluvoxamine maleate shows maximum absorbance at 271 nm. Beer's law was obeyed in the concentration range of 5-25 µg /ml. Results of analysis were validated statistically and by recovery studies. The proposed method is now simple, new, environmentally friendly, accurate and cost-effictive and successfully employed in routine analysis of fluvoxamine maleate tablets. Hydrotropic agent urea did not interfere in spectrophotometric determination.

Keywords: Fluvoxamine Maleate, Hydrotropy, Urea, organic solvent, Spectrophotometer

INTRODUCTION

The term "hydrotropy" has been used to designate the increase in solubility of poorly water soluble drugs in concentrated solutions of hydrotropic agents. A huge number of poorly water-soluble drugs have been solubilized by use of various hydrotropic solutions. Sodium benzoate, sodium salicylate, nicotinamide, urea, sodium ascorbate, sodium acetate and sodium citrate are the most commonly used hydrotropic agents. Review of literature shows that a large number of poorly water-soluble drugs have been analyzed viz. frusemide[1], cefixime[2], salicylic acid[3], ketoprofen[4], tinidazole[5], aceclofenac[6], amoxicillin[7], ofloxacin[8], hydrochlorthiazide[9], metronidazole[10], nalidixic acid[10], ibuprofen[11], naproxen[11], flurbiprofen[11], aspirin[12], cephalexin[13], paracetamol[14], and piroxicam[15] using hydrotropic solubilizing agents. Using hydrotropy fluvoxamine maleate is analyzed in bulk drug and tablet dosage forms.

Fluvoxamine [(E)-5-methoxy-4'-trifluoromethyl valerophenone O-2-aminoethyloxime] or 2-[({(1E)-5-methoxy-1-[4-(trifluoromethyl) phenyl] pentylidene} amino) oxy] ethanamine maleate is selective serotonin reuptake inhibitor as antidepressant. It is sparingly soluble in water. Aqueous solubility of fluvoxamine maleate is increased in 10 M urea solution (more than 10-15 fold enhancement in aqueous solubility as compared to solubility in distilled water). Thus, it was thought worthwhile to solubilize the poorly water-soluble fluvoxamine Maleate, from fine powder of its crushed tablets by 10 M urea solution to carry out spectrophotometric estimations. In most of the hydrotropic solubilization studies it was assumed that the enhancement in solubility of drugs was due to "salting in" effect or due to change in solvent character. The proposed investigation is undertaken with the aim of developing UV Spectrophotometric technique for the analysis of springly water soluble drug from single component formulations.

A Shimadzu UV/Visible recording spectrophotometer (model UV-1800) with 1-cm matched silica cells was employed.

Fluvoxamine maleate was supplied as gift sample by Sun Pharma Laboratories. Ltd., Jammu. Commercial tablets of Fluvoxamine maleate were procured from a local pharmacy as Fluvator-50 mg (Torrent Pharma) and Sorset-100 mg (Ranbaxy ltd.). All other chemicals used were of analytical grade.

Solubilities of fluvoxamine maleate were determined at 27 ± 1^0C in 10 M urea solution, distilled water and buffer of pH 10.0. Sufficient excess amount of drug was added to screw-capped glass vials of 30 ml capacity, containing distilled water, buffer of pH 10.0 and 10 M urea solution. The vials were shaken mechanically for 12 hours at 27 ± 1^0C in orbital shaker (Khera Instrument Pvt. Ltd., India). The solutions were allowed to equilibrate for next 24 hours and then centrifuged for 5 min at 2000 rpm. The supernatant of each vial was filtered through Whatman filter paper No. 41. Filtrates were diluted suitably and analyzed against corresponding solvent blanks.

Twenty tablets of formulation-I (Fluvator) were weighed and powdered. Powder equivalent to 50 mg Fluvoxamine maleate was transferred to a 50 ml volumetric flask containing 40 ml of 10 M urea solution. The flask was shaken for about 5 min to solubilize the

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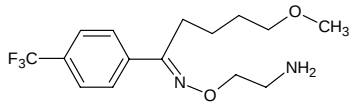

2-{[(*E*)-{5-methoxy-1-[4-(trifluoromethyl)phenyl]pentylidene}amino]oxy}ethanamine

Figure : 1 Structure of fluvoxamine

drug. Then volume was made upto the mark with distilled water. Solution was filtered through Whatman filter paper No. 41. filtrate was divided in two parts, A and B. part A was kept at room temperature for 48 hours to check the effect on stability of drug in presence of urea and also to note precipitation, if any, during this period.

Table 1: Results Of Analysis Of Commercial Tablets Of Fluvoxamine Maleate

Tablet formulation	Label claim (mg)	% Label claim estimated* (Mean ± S.D.)	% Coff. Of variation	Standard error
I (Flvator)	50	98.63 ± 0.885	0.892	0.442
II(Sorset)	100	101.28 ± 0.987	0.974	0.403

*Average of six determinations

Part B filtrate was appropriately diluted with distilled water and absorbance was noted at 271 nm (λ_{max}) against solvent blank and the drug content was calculated (Table 1). After 48 hours, filtrate of part B was also appropriately diluted with distilled water and analyzed for drug content. There was no precipitation in the filtrate in 48 hours. Similar procedure was adopted in case of formulation-II (Sorset) and drug content was calculated (Table 1).

In order to check the accuracy, reproducibility and the precision of the proposed method, recovery studies were performed by adding powder of bulk drug in dosage form. Preanalyzed tablet powder (Formulation-I) equivalent to 50 mg of fluvoxamine maleate was transferred to 50 ml of volumetric flask .Pure fluvoxamine maleate drug sample(20 mg) was added and flask was shaken for 5 min to solubilize the drug. The volume was made upto the mark with distilled water. Then solution was filtered through Whatman filter paper No. 41. The filtrate was diluted with distilled water appropriately and absorbance was noted at 271 nm against corresponding reagent blank. Drug content was calculated and percent recovery was calculated (Table 2). Similar procedure was repeated using same way. The drug content was determined and percent recovery was estimated (Table 2).

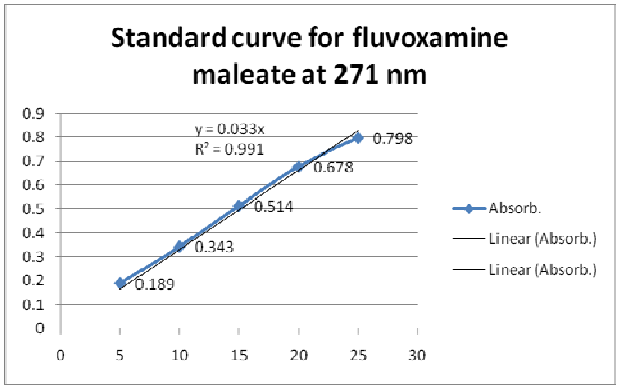

Fig 2: Standard curve for fluvoxamine maleate at 271 nm

The mean percent label claims estimated by proposed method for tablet formulations I and II were 98.63 and 101.28, respectively which are very close to 100, indicating the accuracy of the method. This also indicates that there was no interference of urea and the commonly used additives present in the tablet formulation in the estimation by the proposed method. Validation of the proposed method is further confirmed by the low values of standard deviation, percent coefficient of variation and standard error (Table 1).

The mean percent recovery values ranged from 98.75 to 98.96 and were very close to 100. Also the values of statistical parameters viz. standard deviation, percent coefficient of variation and standard error were significantly low (Table 2). Thus, the proposed method of analysis was very well validated.

Thus, it may be concluded that the proposed method of analysis, using urea as the hydrotropic solubilizing agent is new, simple, cost-effective, environmentally friendly, safe, accurate and reproducible. Urea and the commonly used tablet excipients did not interfere in Spectrophotometric estimation at 271 nm. Decided advantage is that organic solvents are precluded but not at the expense of accuracy. The proposed method is worth adopting in pharmacopoeia. By proper choice of hydrotropic agents, the use of organic solvents in analysis may be discouraged to a large extent.

ACKNOWLEDGMENTS

Authors are grateful to Suresh Kalwania (Senior Chemist) and M/s. Sun Pharma Lab, Jammu for providing the gift samples of drugs. Authors are also thankful to Dr. R.K. Maheshwari for valuable

Table 2: Recovery Studies Of Commercial Tablets Of Fluvoxamine Maleate

Tablet formulation	Label claim (mg)	Drug added (mg)	% Label claim estimated* (Mean ± S.D.)	% Coff. Of Variation	Standard error
I (Flvator)	50	20	98.75 ± 1.486	1.505	0.607
II(Sorest)	100	40	98.96 ± 0.870	0.879	0.435

*Average of six determinations

suggestions.

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