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Visible spectrophotometric estimation of duloxetine hydrochloride in Pharmaceutical formulations

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Abstract
A simple, sensitive, precise and economical visible spectrophotometric method has been developed for the determination of duloxetine hydrochloride in pharmaceutical formulations. The method was based on the formation of chloroform extractable complex of duloxetine hydrochloride with wool fast blue, which shows absorbance maxima at 585 nm against the reagent blank treated similarly. The method obeys Beer's law in the concentration ranges of 50-250 µg/ml. Validation studies are statistically significant as all the statistical parameters are within the acceptance range (% RSD< 2.0 and S.D. < 2.0) for both accuracy and precision study. High recovery and low % RSD reveals the reliability of the method for quantitative study of the proposed method in tablet formulation.. The proposed method was found to be simple, sensitive, accurate, precise, rapid and economical for the routine quality control application of duloxetine hydrochloride in pharmaceutical formulations.
Key words: Duloxetine hydrochloride, Wool Fast Blue, Spectrophotometer, Formulations

Introduction
Duloxetine is chemically as, N-methyl-3-(1-napthyloxy)-3-(thiophen-2-yl)-propan-1-amine. It belongs to the class nar-coleptics. Duloxetine hydrochloride is a newer selective sero-tonin and nor epinephrine reuptake inhibitor used for major depressive disorders. It has been approved for the treatment of major depressive disorder and for the diabetic peripheral neuropathic pain. Duloxetine it is effective for major depres-sive disorder and generalized anxiety disorder. Various methods in literature were reported for the determination of duloxetine hydrochloride which includes HPLC method[1-3], spectroflourimetric method[4,5], HPTLC[6], RP-HPLC[7,8] and spectrophotometric method[9-16]. In the present work, the ion pair complex is formed by the interaction of drug with Wool fast blue. Wool fast blue is insoluble in water and soluble in chloroform.

The organic layer is extracted from chloroform and the absorbance of organic layer is measured at 585 nm against chloroform blank. In developing the proposed method a systematic study of the effects of various relevant parameters in the methods concerned, concentration of reagents, order of addition, time and temperature required for reaction, p^H of buffer, nature of solvents for final dilution, stability of reagents of the coloured species are undertaken by varying one parameter at a time and controlling all other parameters to get a maximum colours development and minimum black colours, reproducibility and the reasonable period of stability of final coloured species formed. After systematic and detailed study of the various parameters mentioned above, the following procedure is recommended for the determination of duloxetine hydrochloride in bulk samples and pharmaceutical formulations.

Materials and Methods
Apparatus
A Milton Roy 1001 plus spectrophotometer with 1 cm quartz cells was used for all measurements.

Reagents and Materials

All the chemicals and reagents used were of AR grade. Double distilled water was used throughout the investigation was used to measure absorbance of all the solutions. The commercially available capsules of Duloxetine hydrochloride were procured from local market labeled to contain 40 mg Duloxetine. AR grade chloroform is used throughout the investigation.

Buffer solution (p^H 1.5):

Buffer solution is prepared by mixing 289 ml of glycine solution (37.52 gm of glycine and 29.24 gm of Nacl are dissolved in 500ml of distilled water) with 711ml of 0.1 M Hcl.

Wool fast blue solution: (0.2% W/V):

Wool fast blue solution is prepared by dissolving 200mg of wool fast blue (Flaka) in 100 ml of distilled water

Preparation of Standard Stock Solution

Duloxetine hydrochloride 100 mg was accurately weighed and dissolved in 100 mL of methanol to form a stock solution (1000 µg/mL). The stock solution was further diluted suitably with methanol to get a working standard solution of concentration 100 µg /mL.

Preparation of calibration curve

Aliquots of standard drug solution of duloxetine hydrochloride 0.5 – 2.5 mL were taken and transferred into a series of 125 mL of separating funnels. To each funnel 1.0 mL buffer solution and 0.5 mL of 0.2% wool fast blue was added. Reaction mixture was shaken gently for 5 min. Then 5 mL of chloroform was added to each of them. The contents were shaken thoroughly for 5 min and allowed to stand, so as to separate the aqueous and chloroform layer. Colored chloroform layer was separated out and absorbance was measured at 585 nm against reagent blank. Calibration curve was plotted from absorbance values against concentration of drug (Figure 1).

Analysis of Duloxetine in Pharmaceutical Preparation

For analysis of tablet formulation, twenty tablets of duloxetine hydrochloride are weighed accurately and finely powdered. An accurately weighed portion of powdered sample, equivalent to 50 mg of duloxetine was taken in a 50 ml volumetric flask containing 25 ml of methanol, sonicated for 20 minutes. The resultant solution is filtered through Whatman filter paper No. 41 into another 50 ml volumetric flask. The filter paper was washed several times with methanol. The washings were added to the filtrate and the final volume was made up to the mark with methanol. Further sample solution is diluted and treated as per the procedure of the calibration curve. Amount of the drug present in sample was computed from respective calibration curve. The results are present in table.1.

Recovery Studies

To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed method and also performed recovery experiments. The percentage recoveries thus obtained were given in Table 1.

Results and Discussions

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen**.** In the present work the method was developed for the estimation of duloxetine hydrochloride from tablet formulations. The developed method is based on formation of chloroform extractable colored complex with wool fast blue. The conditions required for the formation of colored complexes were optimized. Recovery studies were close to 100 % that indicates the accuracy and precision of the proposed methods. The calibration curve is linear over the range of 50-250 µg/ml of duloxetine hydrochloride. Statistical analysis of commercial formulations has been shown in Table1. The percent relative standard deviation calculated from the five measurements of duloxetine hydrochloride shown in Table 1. The % RSD is less than 2, which indicates that the method has good reproducibility. The values of standard deviation values are low, indicates high accuracy and reproducibility of the method. The‘t’ calculated values are compares well with the theoretical value of 2.78 there by indicating that the precision of the method. There is no effect of additives and excipients such starch, calcium lactose and glucose in the concentrations those present in general pharmaceutical preparations.

Table.1. Assay of duloxetine in pharmaceutical formulations

Tablets	Labeled amount(mg)	*Amount found ±S.D	% Recovery	%RSD*	*t value
Tablet 1	40	39.99±0.13	99.98	0.3305	0.1692
Tablet 2	40	40.04±0.26	100.1	0.6622	0.3378
Tablet 3	40	40.08±0.25	100.2	0.6422	0.6908

***Average of five determinations**

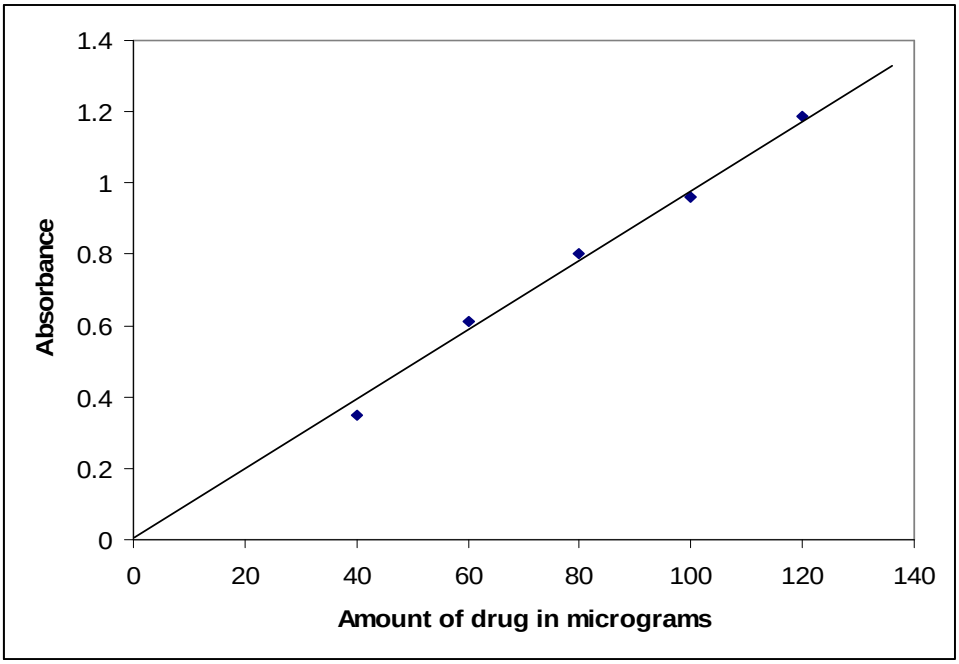

Figure.1. Calibration curve of duloxetine hydrochloride

Conclusion

The proposed method[3]Department of physics, Osmania College, Kurnool, AP, India are simple, sensitive, accurate and economical for the routine estimation of duloxetine hydrochloride in bulk and in its tablet dosage form.

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