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Colourimetric Assay of Atomoxetine Hydrochloride by Simple Aurum Coupling Reaction in Bulk and Tablet Dosage Form

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Abstract

Simple, rapid and sensitive spectrophotometric procedure was developed for the analysis of atomoxetine hydrochloride (ATH) in pure form as well as in pharmaceutical formulations. The method was based on the reaction of ATH with gold (III) chloride in the pH range 3.5-4.5 forming violet colored complex solution, showing absorption maxima at 550 nm. The linear plot indicates that Beer?s law is obeyed in the range of 5 â?? 80 ?g/ml of atomoxetine hydrochloride. The molar absorptivity and Sandell?s sensitivity are 3.77 x 103M and 0.0774 ?g cm-2 respectively. The standard deviation of the method for ten determinations ATH is 9.9827 x 103. The correlation coefficient (r2) of the experimental data of the calibration plot is 0.9997. The effective range of concentration for accurate determination of ATH as ascertained from Ringbom?s plot and it is 10 â?? 80 ?g/ml.

Index terms— atomoxetine hydrochloride, spectrophotometric, ringbom?s plot, pharmaceutical formulations.

It is practically a white solid and has a solubility of 27.8 mg ml-1 in water. It is the first nonstimulant drug approved by the FDA for the treatment of attentiondeficit hyperactivity disorder (ADHD) in children, adolescents and adults. ADHD is the most common neurobehavioral disorder among children with an estimated worldwide prevalence of 8-12%1.

ATH is not official in IP, BP, USP and EP. AMX is available commercially as capsules under brand name Straterra, Eli Lilly and company capsules. AMX capsules are intended for oral administration only. The capsules are available with strengths of 10, 18, 25, 40, 60 and 80 mg of ATH base. The capsules also contain pregelatinized starch and dimethicone.

A number of analytical methods based on liquid chromatography with fluorescence detection2, liquid chromatography/mass spectrometry/mass spectrometry 3-6 (LC/MS/MS) have been developed for the determination of atomoxetine in human plasma and urine. A chiral analytical method by using HPLC with UV7 has been reported for the determination of AMX impurities.

To the best of our knowledge, there is no work in the literature reported about the colourimetric method for the analysis of ATH in pharmaceutical formulations. Hence the author has made an attempt to develop simple and sensitive spectrophotometric method for the estimation of ATH in bulk drugs and in pharmaceutical formulations. The method was based on the reaction with gold(III) to form a violet coloured complex in the pH range 3.5 -4.5.

1 II.

2 Materials and Methods

All chemicals used were of analytical reagent grade and double distilled water was used for preparing the reagent solutions. ATH was obtained from Dr. Reddy's labs Hyderabad. Stock solution of ATH was freshly prepared by dissolving 100mg of ATH in 100mL of distilled water and then this was further diluted with distilled water so as

to obtain working standard solution of 100 ?g/mL. To explore the possibility of employing the colour reaction for the determination of gold(III) in trace level, the absorbance of the experimental solutions containing different amounts of gold(III), keeping the ATH concentration in excess, is measured in the wavelength range 400 -700 nm.

3 c) Assay of Pharmaceutical dosage form of Atomoxetine hydrochloride

The present method for the determination Atomoxetine hydrochloride is applied for its determination in a pharmaceutical sample. A know aliquot of pharmaceutical sample solution of atomoxetine hydrochloride is added to a 10 ml volumetric flask containing 5ml of buffer solution of pH 4.0 and 0.5 ml of gold(III) (5.0 x 10-3M) solution 1.5 ml of 2% SDS solution. The contents are made upto the mark with distilled water. After heating for 60 minutes at 650C and cooling the solution to room temperature. The absorbance of the resulting solution is measured at 550 nm against the buffer blank. The amount of atomoxetine hydrochloride is computed from the predetermined calibration plot at 550 nm.

IV.

4 Results and Discussion

The spectra presented in fig 2 show that the complex has an absorption maximum at 550 nm. Neither gold (III) nor atomoxetine hydrochloride have absorbance at 550 nm. Hence, analytical studies are made at 550 nm. However, in presence of excess atomoxetine hydrochloride the complex shows maximum absorbance at 550 nm. The molar absorptivity and Sandell's sensitivity are 3.77 x 103 l mol-1 cm-1 and 0.0774 µg/cm2 respectively. The standard deviation of the method for ten determinations of 10 µg/ml of atomoxetine hydrochloride is 9.9826 x 10-4.

The correlation coefficient (?) of the experimental data of the calibration plot is 0.9997. The effective range of concentration for accurate determination of atomoxetine hydrochloride as ascertained from Ringbom's plot and it is 10.0 -70.0 µg/ml.

5 B

out under optimal conditions. The concentration (µg/ml) at which various ions do not cause an error of more than ± 4% in the absorbance is taken as the tolerance limit and the results are given in table 1.

Table **??** : Tolerance limit of excipients Amount of AMX = 10 µg/ml ; pH = 4.0

6 Excipient

Tolerance limit (µg/ml) The data in table1 indicate that the excipients that are associated with atomoxetine hydrochloride do not interfere even in large quantities in the determination of atomoxetine hydrochloride making the method highly selective and direct.

7 c) Assay of atomoxetine hydrochloride

The present method for the determination atomoxetine hydrochloride is applied for its determination in the tablet dosage form. The amount of atomoxetine hydrochloride is computed from the predetermined calibration plot at 550 nm. The results are presented in table 2

8 Conclusions

Atomoxetine hydrochloride reacts with gold(III) to form stable violet coloured 1 : 1 complex at pH 4.0. Spectrophotometric and derivative spectrophotometric methods are developed based on this reaction. They are sensitive for the assay of both atomoxetine hydrochloride and gold(III). The tolerance limit of the excipients and the foreign ions in derivative methods is found to be generally 10 -20% greater than that of the zero order method. The present spectrophotometric methods are direct, simple and highly selective for the determination of gold(III) or atomoxetine hydrochloride. Further, the methods can easily be employed by ordinary clinical laboratories as the methods can be carried out using a simple colorimeter. [1] [2] [3]

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[3] ( ) B Colourimetric Assay of Atomoxetine Hydrochloride by Simple Aurum Coupling Reaction in Bulk and Tablet Dosage Form

Figure 1:

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pharmaceutical formulation Sample (manufacture r formulation)	Label claim (mg)	Amount found * (mg)	Error (%)
Straterra, Eli Lilly and company	10.00	9.91	-0.90

* Average of seven determinations

Optimal characteristics, accuracy and precession, data of the determinations of atomoxetine hydrochloride and gold (III) are presented in table. 3.

Figure 2: Table 2 :

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hydrochloride and gold(III)
[AMX] = 3.42 x 10-3M ; pH = 4.0
[Au(III)] = 5.0 x 10-3M ; ? = 550 nm

Parameter	Atomoxetine hydrochloride	Gold(III)
Analytical wavelength (nm)	550	530
Beer's law limits (µg/ml)	5.0 -80.0	9.84 - 157.42
Limits of detection (µg/ml)	2.2837	10.3723
Limits of quantization (µg/ml)	7.6170	34.7446
Molar absorptivity (lmol -1 cm -1)	3.77 x 10 3 M	0.75 x 10 3 M
Sandell's sensitivity (µg cm -2)	0.0774	0.2625
Regression equation (y = a + bx)		
Slope (b)	0.0129	0.0047
Intercept (a)	-0.0009	0.0104
Correlation coefficient (?)	0.9997	0.9981
Standard Deviation (SD)	9.9827 x 10 3	0.0163

V.

Figure 3: Table 3 :

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