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DEVELOPMENT AND VALIDATION OF DIFFERENCE SPECTROSCOPIC METHOD FOR DETERMINATION OF BUPROPION IN ITS TABLET DOSAGE FORM

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ABSTRCT

A simple, accurate & precise difference spectroscopy method was developed for determination of Bupropion in its pharmaceutical dosage form. The proposed method depends upon measuring the amplitude of absorbance on difference spectra of Bupropion in 0.001N NaOH and 0.001N HCl at 234nm and 254nm respectively. The calibration curve linear over the range 2.5-30 µg/ml with correlation coefficient (r) 0.9998. The percentage of recovery found to be 99.20-98.30%. The developed method validated statistically and was applied successfully for routine analysis of Bupropion in its Tablet Dosage form.

KEYWORDS: Bupropion, Difference spectroscopy, Antidepressant.

INTRODUCTION

Bupropion(BUP), (±)-2-(tert-butylamino)-1-(3chlorophenyl)propan-1-one. It is dopamine - noradrenaline reuptake inhibitor and has also been shown to act as a noncompetitive α3β4 nicotinic antagonist primarily used as an antidepressant and smoking cessation aid.It is also used in Sexual dysfunction Obesity, Attention-deficit hyperactivity disorder, Crohn's disease and Mood stabilizer in patients with bipolar depression.[1-3]

Literature survey revealed that some various bioanalytical methods have been reported for Bupropion, which includes HPLC& UPLC/MS/MS, LC/MS/MS in Human Plasma[4-6], HPLC in dog plasma[7],LC-MS in Rat Plasma., Spectrophometric, HPLC, and stability studies in UV[8-12] in Tablet dosage form.

To the best of author's knowledge, Differerance spectroscopic method development not yet been reported for estimation of BUP. So, it was thought of interest to develop such an approach for the quantitative analysis of BUP in pharmaceutical formulation.

MATERIALS AND METHODS

Bupropion pure powder was obtained as a gift sample from Cadila Healthcare Limited (Ahmedabad, India). All the reagents used were of AR grade and procured from S. D. Fine chemicals. A Shimadzu UV-1700 double beam UV-Visible spectrophotometer attached with computer operated software UV probe 2.0 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. A Sartorius (CP224S) analytical balance and ultrasonic cleaner (Frontline FS-4) sonicator were used during the study. Tablets of Bupropion were purchased from local pharmacy.

A standard stock solution of Bupropion (1mg/ml) was prepared by dissolving 100 mg pure drug in 100ml volumetric flask with 0.001N HCl: Methanol (80:20) as diluent. Aliquots of working standard (100 µg/ml) solution of Bupropion were suitably diluted with diluents to obtain the final concentration in the range of 2.5-30 µg/ml. The amplitude of absorbance of difference spectra of Bupropion in 0.001N NaOH and 0.001N HCl at 234nm and 254nm respectively was used for measurement. Linear correlation was obtained by plotting Amplitude of absorbance versus concentrations of Bupropion.

For analysis of Bupropion in tablet dosage form, ten tablets were accurately weighed and powdered for analysis. A quantity of accurately weigh powder equivalent to 100 mg of Bupropion was transferred to a 100 ml volumetric flask, sonicated for 15 minutes with diluent to dissolve the drug as completely as possible and diluted up to to100 ml with diluent. This resulting solution was diluted to produce 100 µg/ml of sample solution .Again suitable aliquots from 100 µg/ml further diluted to achieve 20 µg/ml. The solution was filtered through 0.45 µ Millipore PVDF filter; filtrate was collected after discarding first few ml.

RESULT AND DISCUSSION

Method development

In Difference spectroscopic method the absorption spectra of equimolar solutions of Drug in two different pH (acidic, basic or neutral) were taken (Fig.1). The difference absorption

spectrum is a plot of the difference in absorbance between the solutions against wavelength. It may be generated automatically using a double beam recording spectrophotometer with the solution 1 in the sample cell and the solution 2 in the reference cell (Fig. 2). The absorbance was measured at two wavelengths, one being the peak maxima and other being peak minima. For this measurement, equimolar solution of Bupropion was prepared separately in 0.001 N HCl as well as in 0.001 N NaOH at a concentration of 20 µg /ml. They were scanned in the wavelength range of 200-400 nm. Data were recorded at an interval of 1 nm. From the difference spectrum of drug in two different form, absorbances were measured at selected wavelength i.e. 234 nm Peak maxima and 258 nm Peak minima. The amplitude, which is sum of magnitude of absorbances at above two wavelengths, was selected for the measurement. It was calculated and used to obtain the concentration. The isobestic points (points representing zero absorbance corresponding to cutting points of acidic and alkaline spectra) was recorded at 244 nm ,which were identical irrespective of the pH of solution in reference cell. There was no change in isobestic points, which reveals that there was no interference by additives.

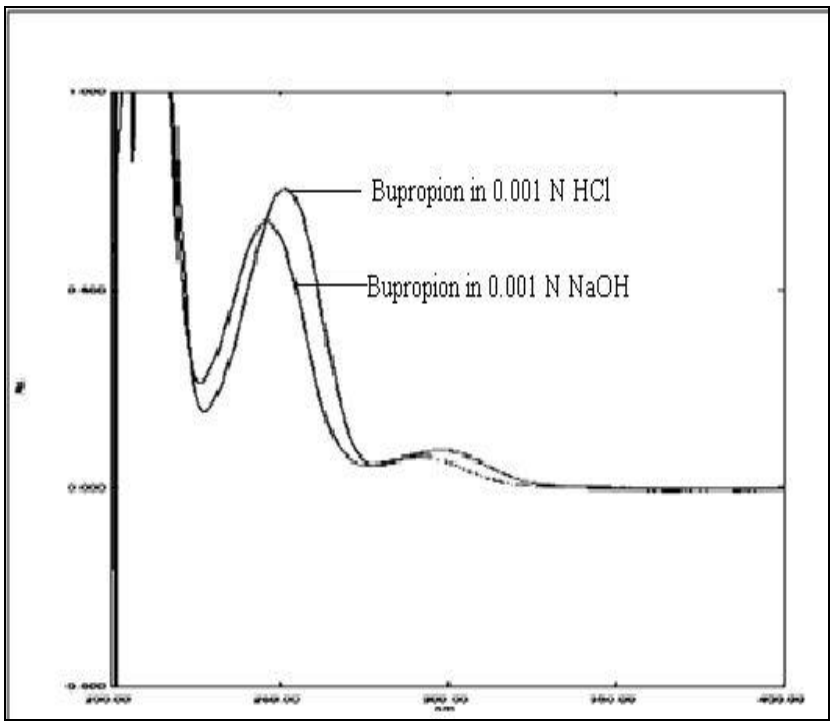

Fig.1 overlain absorption spectra of bupropion in 0.001N NaOH and in 0.001N HCl.

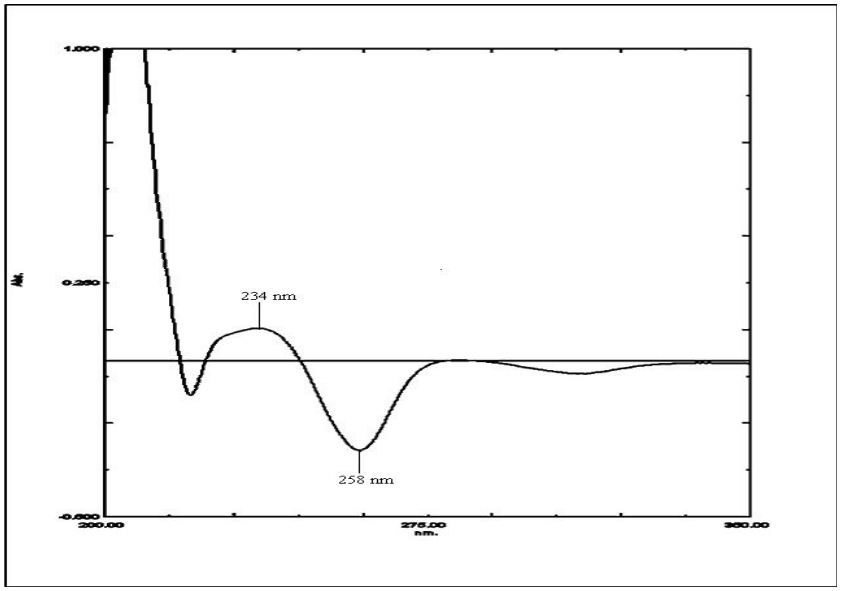

Fig. 2 difference absorption spectra of basic solution of bupropion against acidic solution.

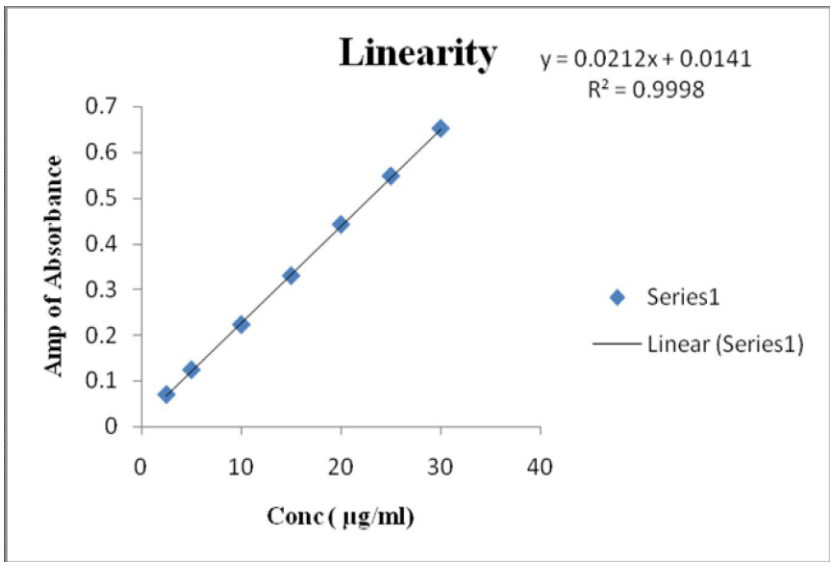

Fig 3 calibration curve of bupropion by difference spectroscopic method

The developed method was validated as per ICH guidelines [12] and validation parameters are summarized in Table 1.

Linear correlation (fig.3) was obtained between Amplitude of absorbance at 234nm & 258nm versus concentrations of Bupropion in the ranges of 2.5 – 30 µg/ml.

Recovery studies were done by spike placebo method by adding known quantity of drug (50 %, 100 % and 150 % levels) to placebo mixtures were sonicated and filtered through 0.45µ filter then analyzed by proposed method.

The low values of % RSD for intraday and interday precision indicate that the method was precise and reproducible. The LOD and LOQ values were calculated based on signal to noise ratio equation as per ICH guidelines.Low value of LOD and LOQ describe the method as sensitive.

The assay results obtained was 99.9 ± 0.19 (Table 2), indicate the excipients do not interfere during the analysis normally present in the tablet.

Table 1.Regression analysis data and validation parameters by proposed Difference Spectroscopic method

Parameters		**Bupropion**
Linearity		2.5-30 µg/ml
Regression equation y=mx+c		y = 0.0212x +0.0141
Slope(m)		0.0212
Intercept(c)		0.0141
Correlation coefficient (r^2)		0.9998
LOD (µg/ml)		0.83
LOQ (µg/ml)		2.5
Accuracy(% recovery)±RSD (n=3)	50 %	99.2±0.5
	100 %	99.9 ± 0.1
	150 %	98.3± 0.2
Repeatability (%RSD,n=6)		1.5
Precision (%RSD)		
Interday (n=3)		0.21% -1.59%
Intraday (n= 3)		0.54%-1.87%

[a]Limit of detection,[b]Limit of quantification ,[c]Relative standard deviation

Table 2.Analysis of bupropion in tablets by proposed difference spectroscopic method

Formulation	**Label Claim (mg)**	**Amount found**	**% Assay*± SD**
Tablet	300	299.70	99.9±0.19

*Avarage of three determination,[d]Standard deviation

CONCLUSION

Based on the results, obtained from the analysis of Bupropion using described method, it can be concluded that Bupropion has linear response in the range of 2.5 – 30 µg/ml with coefficient of correlation, (r^2) = 0.9998 by this method.

The result of the analysis of pharmaceutical formulation by the proposed method is highly reproducible and reliable and is in good agreement with label claim of the drug. The additive usually present in the pharmaceutical formulations of the assayed sample did not interfere

with determination of Bupropion. The method can be used for the routine analysis of Bupropion in dosage form.

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