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SPECTROPHOTOMETRIC DETERMINATION OF HALOPERIDOL IN PHARMACEUTICAL FORMULATIONS

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ABSTRACT

A simple, sensitive, rapid and accurate colorimetric method has been developed for the estimation of haloperidol in pharmaceutical formulations. The proposed method was based on the formation of chloroform extractable complex of haloperidol with phenol red. The absorbance of the extractable ion pair complex is measured at the wavelength of maximum absorbance 485 nm against the reagent blank. Results obtained are statistically validated and found to be reproducible.

KEYWORDS: Spectrophotometry, phenol red, haloperidol, Pharmaceutical and Formulation.

INTRODUCTION

Haloperidol is the first of the butyrophenone series of major antipsychotics. The chemical designation is 4-[4-(p-chlorophenyl)-4-hydroxypiperidino]-4'-fluorobutyrophenone. Molecular formula of haloperidol is C21H23ClFNO2. Molecular weight of haloperidol is 375.9g/mol. It is freely soluble in chloroform, methanol, acetone, benzene, dilute Several analytical methods have been reported for assay of haloperidol including spectrophotometric method[1-9], RP-HPLC method[10,11], HPLC[12,13], Gas Chromatography method[14], Spectrofluotometry method[15], Absorption method[16], Electrode conductivity method.[17] This paper describes a rapid, simple, sensitive and economical spectrophotometeric methods for the determination of haloperidol in phamaceutical formulations forms. This method based on the formation of chloroform extractable complex of haloperidol with phenol red. The ion association complex is a special form of molecular complex resulting from two components extractable into organic solvents from aqueous phase at suitable pH. One component is a

chromogen (Phenol red processing charge (Cationic or anionic in nature) & so insoluble in organic solvents. The other is colorless, processing opposite charge to that of chromogen. The main purpose of the present study was to establish relatively simple, sensitive and validated visible spectrophotometric methods for the determination of haloperidol in pharmaceutical dosage forms.

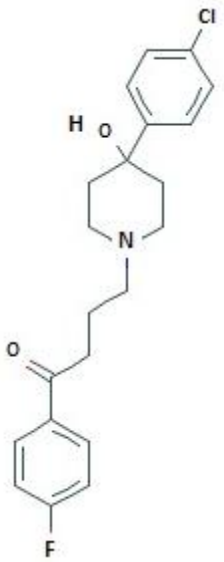

Fig. 1: The chemical structure of haloperidol.

MATERIALS AND METHODS

Instrument

All measurement were done on Milton Roy 1001spectrophotometer by using 10 mm matched quartz cuvettes.

Materials

All chemicals used are of A.R. grade and were purchased from S.D. fine chemicals and LOBA-Chemi, Mumbai. Doubled distilled water were used for preparation of solutions.

Buffer solution (p^H 3.6)

Buffer solution (pH 3.6) is prepared by mixing 100 ml of 0.1 M potassium hydrogen phthalate (20.422 gm of Potassium Hydrogen Phthalate (Fischer scientific) in 1000 ml of distilled water) in 12.6 ml of 0.1M HCl(10 g of 36% HCl (Merck) is dissolved in 1000ml of distilled water) and pH of the solution is adjusted to pH 3.6.

Preparation of standard stock solution

The standard stock solution (1mg/ml) of haloperidol was prepared by dissolving 100 mg of AM in 100 ml distilled water. The working standard solutions of haloperidol were obtained by appropriately diluting the standard stock solution with the same solvent.

Preparation of Calibration curve

Aliquots of standard drug solution of haloperidol 0.5 – 2.5 ml were taken and transferred into a series of 100 ml of separating funnels. To each funnel 2 ml of 0.2% phenol red was added. Reaction mixture was shaken gently for 5 min. Then 10 ml of chloroform was added to each of them. The contents are 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 485 nm against reagent blank. The calibration graph was constructed by plotting the drug concentration versus absorbance (Fig.2). The amount of drug was computed from its calibration graph. (fig 2).

Assay of pharmaceutical Formulations

About 20 tablets were weighed to get the average tablet weight and pulverized. The powder equivalent to 100 mg of haloperidol was weighed, dispersed in 25ml of methnol, sonicated for 15 minutes and filtered through Whatman filter paper No 41.The filtrate was evaporated to dryness and the residue was dissolved as under standard solution preparation and analyzed using the procedure described earlier.

RESULTS AND DISCUSSION

Haloperidol was treated with phenol red dye at 3.6 pH. The resultant solution is extracted with chloroform. The ion pair complex is formed in extractable chloroform layer. The absorbance of the extractable ion pair complex is measured at 485 nm against the reagent blank. The calibration curve was linear over the range of 50-250 µg/mL of haloperidol. The proposed method was validated statistically. The molar absorptivity and Sandell's sensitivity values show the sensitivity of method. Assay results are given in table2. Results are in good agreement with labeled value. The reproducibility, repeatability and accuracy of this method were found to be good, which is evidenced by low standard deviation.

The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results are summarized in table 1. The optical characteristics such as absorption maxima, Beer's law limits, molar

absorptivity, Sandell's sensitivity were calculated and the results are summarized in Table 1. The 't' calculated values are compares well with the theoretical value of 2.78 there by indicating that the precision of the method. These studies revealed that the common excipients and other additives such as starch, talc, lactose and magnesium stearate, that are usually present in tablet dosage forms, did not interfere at their regularly added levels orated in the procedure.

Table 1: Optical Characteristics of the Proposed Method.

Parameters	**Proposed Method**
Wavelength (nm)	485
Beer's limits, mcg/ml	50-250
Sandell's, sensitivity, (µg cm^{-2})	0.1127
Molar absorptivity, (L mol^{-1} cm^{-1})	$1.22x10^2$
Regression equation, Y*	Y= 0.0187x+0.0013
Correlation coefficient, (r)	0.9999
Intercept (a)	00187
Slope (b)	0.0013

Table 2: Assay and Recovery of Haloperidol in Pharmaceutical Formulations.

Formulation	**Labeled amount**	***Amount found (mg±S.D)**	**% Label Claim**	***t value**
Tablet 1	10	10.09±0.07	100.9	0.7165
Tablet 2	10	10.21±0.2	102.1	1.970
Tablet 3	10	10.19±0.14	101.0	1.411

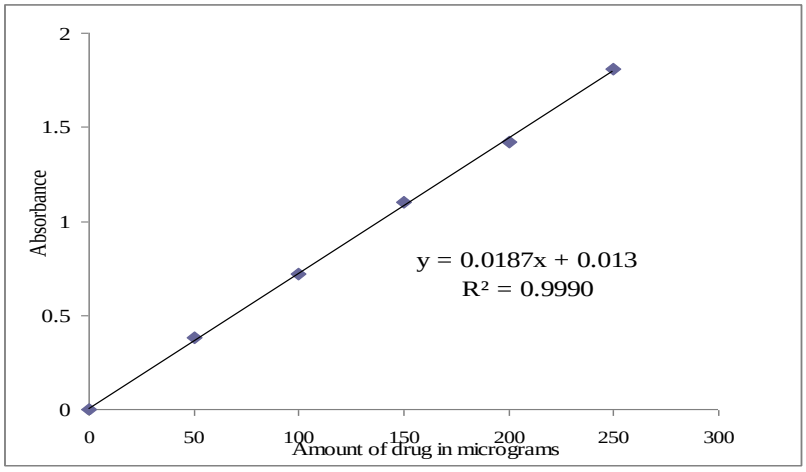

Fig. 2: Calibration curve of haloperidol.

CONCLUSION

The developed visible spectrophotometric method was simple, sensitive, accurate, precise, and reproducible and can be successfully applied for the routine estimation of haloperidol in bulk and pharmaceutical dosage forms.

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