Asian Journal of Chemistry Vol. 19, No. 1 (2007), 819–820

NOTE

UV Spectrophotometric Determination of Ziprasidone Hydrochloride in Pure and Pharmaceutical Formulation

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Simple and sensitive method has been developed for determination of ziprasidone hydrochloride monohydrate (ZPH) in both pure and pharmaceutical formulation. This method obeys Beer's law in the concentration range of 10–70 μg/mL, exhibiting maximum absorption at 318 nm. In this method no interference from the common pharmaceutical excipients was observed.

Key Words: UV spectrophotometric estimation, Ziprasidone hydrochloride, Sodium lauryl sulfate.

Ziprasidone hydrochloride is a new anti-psychotic agent of benzisothiazole class, developed by Pfizer[1]. Chemically, ziprasidone hydrochloride monohydrate is 5-[2-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl] ethyl]-6-chloro-1,3-dihydro-2*H*-indol-2-one monohydrochloride monohydrate. The empirical formula is $C_{21}H_{21}ClN_4OS{\cdot}HCl{\cdot}H_2O$ and its molecular weight is 467.42. A few HPLC methods[2] have been reported for ziprasidone hydrochloride. Literature survey reveals that no visible and UV methods have been reported for estimation of ziprasidone hydrochloride. An attempt has been made to develop an accurate and reliable UV spectrophotometric method for the estimation of ziprasidone hydrochloride in pure as well as in pharmaceutical dosage forms.

All the chemicals used were of analytical grade. A Thermospectronic UV1, UV-Vis double beam spectrophotometer was used for all absorbance measurements. Literature suggests that ziprasidone hydrochloride has very poor water solubility[3]. The solubility study conducted revealed that ziprasidone hydrochloride has appreciable solubility in NaH_2PO_4 buffer (pH 7.4) containing 2% sodium lauryl sulfate.

100 mg of ziprasidone hydrochloride was accurately weighed and dissolved in 100 mL of methanol. The stock solution was further diluted with NaH_2PO_4 buffer (pH 7.4) containing 2% sodium lauryl sulfate, to obtain a working standard of 100 μg/mL. All the further dilutions ranging from 10–70 μg/mL were made by dilution with NaH_2PO_4 buffer (pH 7.4) containing 2% sodium lauryl sulfate. Aliquots of solution ranging from 1–7 mL were transferred into a series of volumetric flasks and the volume was made up to 10 mL with NaH_2PO_4 buffer (pH 7.4) containing 2% sodium lauryl sulfate. The individual samples were scanned from 200–350 nm, the maximum absorbance was observed at 318 nm, whereas no maximum absorbance

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was observed when all the dilutions of the stock solution in methanol were done by NaH_2PO_4 buffer (pH 7.4) without 2% sodium lauryl sulfate.

Thus the absorbance was measured as 318 nm against a blank reagent. The Beer's law limit, Sandell's sensitivity, molar extinction coefficient, per cent relative standard deviation, regression equation, correlation coefficient were calculated and are shown in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS OF THE PROPOSED METHOD

Parameters	Ziprasidone hydrochloride
λ_{max} (nm)	318
Beers law limit (μg/mL)	10–70
Sandell's sensitivity (μg cm^{-2}/0.001 absorbance unit)	0.0827
Molar absorptivity (L mol^{-1} cm^{-1})	5.877×10^3
Regression equation (Y = a + bc)	
Slope (b)	1.4×10^{-2}
Intercept (a)	-7.0×10^{-2}
Correlation coefficient (r)	0.9994
Relative standard deviation (%)*	0.265

* Average of eight determinations

The results of analysis of pharmaceutical formulation of ziprasidone hydrochloride are presented in Table-2. An accurately weighed tablet powder of ziprasidone hydrochloride equivalent to 100 mg of pure drug was dissolved in 100 mL methanol. This solution was filtered using Whatmann filter paper No. 41 and further diluted with NaH_2PO_4 buffer (pH 7.4) containing 2% sodium lauryl sulfate to obtain a concentration of 50 μg/mL. Recovery studies were carried out to establish the validity and reproducibility of the developed method. Known amount of pure drug was added to the previously analyzed tablet sample and mixtures were analyzed by the proposed method.

TABLE-2
ESTIMATION OF ZIPRASIDONE HYDROCHLORIDE IN PHARMACEUTICAL FORMULATION

Sample	Labelled amount (mg)	Amount found in proposed method (mg)	Recovery (%)
Ziprasidone hydrochloride			
Capsule I	40	40.11	99.28
Capsule II	40	40.06	100.00

Thus it could be concluded that the proposed method is simple, accurate and sensitive. Recovery studies revealed that the method is reproducible. It was observed that determination of ziprasidone hydrochloride was not interfered by the presence of excipients. Thus the present method could be used for determination of ziprasidone hydrochloride both in bulk and pharmaceutical formulation.

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(*Received*: 19 January 2006; *Accepted*: 30 June 2006) AJC-5021