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ORIGINAL ARTICLE **OPEN ACCESS**

Area Under Curve UV- Spectrophotometric Method For Determination of Lurasidone HCl in Bulk

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ABSTRACT
The simple, precise, and accurate UV-Spectrophotometric method has been developed and validated for the estimation of Lurasidone Hydrochloride in bulk. In that work was carried out for estimation of Lurasidone Hydrochloride in bulk by utilizing area under curve (AUC) method. For this purpose the wavelength range 200-400nm was selected. Methanol was used as solvent throughout the work. Linearity was observed in concentration range 5-25µg/ml for the method. The present method was found which can be used for routine quality control analysis for spectrophotometric estimation of Lurasidone Hydrochloride.
Keywords: *Lurasidone Hydrochloride API,Area Under Curve Method, λ max.*

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INTRODUCTION

Lurasidone is an atypical antipsychotic approved by the U.S. Food and Drug Administration(FDA) for treatment of Schizophrenia on October 28, 2010 [1]. Lurasidone Hydrochloride (3aR,4S ,7R,7aS) – -{(1R,2R) –2 -[4 -(1,2 - benzisothiazol-3-yl) piperazin –1– ylmethyl] cyclohexylmethyl } hexahydro - 4, 7-methano -2H isoindole – 1,3 -dione hydrochloride (Fig.1) is a azapirone derivative antipsychotic used in the treatment of schizophrenia[2]. The efficacy of Lurasidone Hydrochloride in schizophrenia is mediated through a combination of central dopamine Type 2 (D2) and serotonin Type 2 (5HT2A) receptor antagonism and it gives Antipsychotic Activity. Lurasidone is metabolized in the liver via the enzyme CYP3A44 [3]. This means that its plasma concentrations may be increased when combined with CYP3A4 inhibitors like ketoconazole or grape fruit juice, possibly leading to more side effects. As with other Atypical Neuroleptics, Lurasidone should not be used in elderly patients because it puts them at an increased risk for a stroke or transient ischemic attack [3,4] .

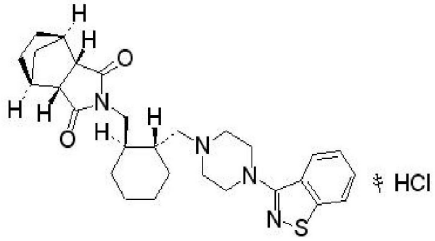

Figure 1: Chemical Structure of Lurasidone Hydrochloride

Literature search reveals following methods reported viz., simple spectrophotometric method for the estimation of Lurasidone in tablet dosage form(5,6) , Simple RP-HPLC method for
quantitative analysis of Lurasidone [7,8,9,10], LCMS method for quantification of Lurasidone in rat plasma and its application in pharmacokinetic studies[11] and Stability Indicating HPLC method for determination of Lurasidone in pharmaceutical dosage form[12] To the best of our knowledge, no area under curve method has been reported for Lurasidone Hydrochloride .The present work describes a simple area under curve method of Lurasidone HCl.

MATERIAL AND METHODS

Chemicals

Lurasidone HCL a gift sample from Flamingo Pharmaceutical, Taloja, Navi Mumbai, India. All chemicals and reagents used were of analytical reagent (AR) grade and purchased from Qualigens Fine Chemicals, Mumbai, India.

Instrumentation

Shimadzu (Kyoto, Japan) model UV- 1800 double beam UV- Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. Analytical balance of make Mettler Toledo (Model JL 1503- C) was used for weighing purpose.

METHOD

Experimental Work

A) To check the solubility ofLurasidone Hydrochloride:

25 mg of Lurasidone Hydrochloridewas weighed and solubility of this sample was checked in 25 ml distilled water, methanol, ethanol. It is freely soluble in methanol, hence solvent selected as a methanol.

B) To identify the λ max of Lurasidone Hydrochloride:

Weighed and transfer10mg of the pure drug and dissolved small portion of methanol and volume was made up to 10 ml using methanol to give a standard stock solution of 1000µm/ml. From above solution 1 ml of the standard solution was withdraw in volumetric flask and diluted to 10 ml with distilled water to prepare 100ppm solution. Suitable dilutions were made with distilled water to get standard solutions of concentrations: 5, 10, 15, 20, 25µm/ml. Spectrum peak details are shown in Figure2 Spectrum peak pick.

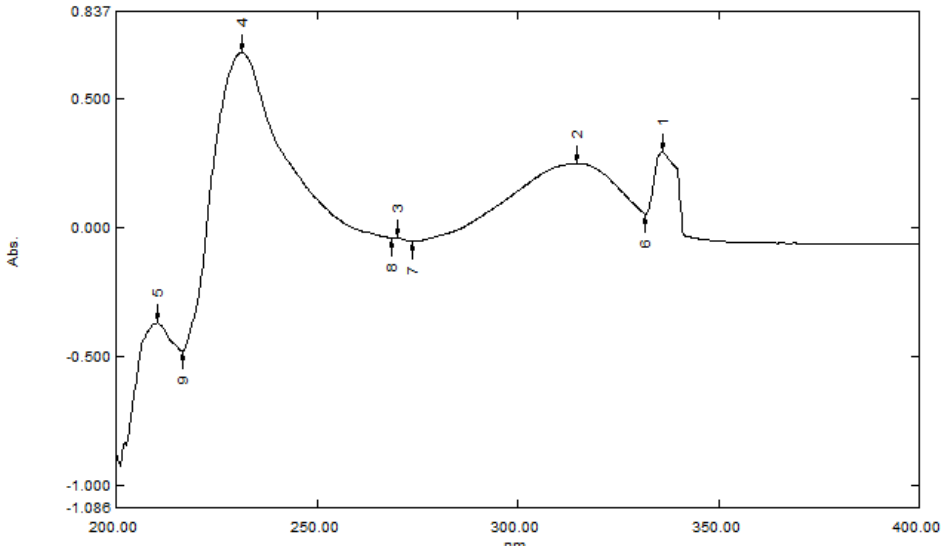

Figure 2: Spectrum peak report of Lurasidone Hydrochloride.

C) Area Under Curve Method:

In case of AUC (Area under Curve) method is applicable where there is sharp peak or broad spectra are obtained. It include the calculation of integrated value of absorbance with respect to the wavelength between the two selected wavelengths λ1 and λ2. Area calculation processing item are calculates the area bound by the curve and the horizontal axis. The horizontal axis is selected by the entering the wavelength ranges over which area has to be calculated. This wavelength ranges are selected on the basis of repeated observations so as to get the linearity between area under curve and concentration. The above mentioned spectrums are used to calculate AUC. Thus, the calibration curve can be plotted concentration versus AUC.

D) Analytical Method Development and Validation:

Linearity:

The linearity of an analytical procedure is the interval between the upper and lower concentration of analyse in the sample. For which demonstrated that the analytical procedure is of linearity. The standard solution of Lurasidone Hydrochloride(5, 10, 15, 20, and 25µm/ml) was pipette out in a separated series of 10ml volumetric flask. Make up the volume with distilled water and mixed well. The absorbance maxima and area under curve for the solutions was measured at 231.20nm and range of 200 – 400 nm for

two methods respectively against distilled water+methanol as blank. Calibration Curve table of Lurasidone Hydrochloride is shown in figure 3.

RESULTS AND DISCUSSION

Calibration Curve for Drug :

Absorbance maxima method:

In the Experimental conditions described, the graph obtained for the absorbance maxima for pure drug showed linear relationship (Figure 2). Regression analysis was made for the slope, intercept and correlation coefficient values. The regression equations of calibration curve were y = 0.105x + 0.003 (r^2 =0.999) at 292.20 nm for absorption maxima the range was found to be 5-25µm/ml for the UV spectrophotometric analysis. Calibration curve of Lurasidone Hydrochloride is shown in Figure. 3.

Table 1: Calibration Curve of Pure Lurasidone Hydrochloride.

Concentration	Absorbance
5 ppm	0.48
10 ppm	0.677
15 ppm	0.812
20 ppm	0.949
25 ppm	1.12

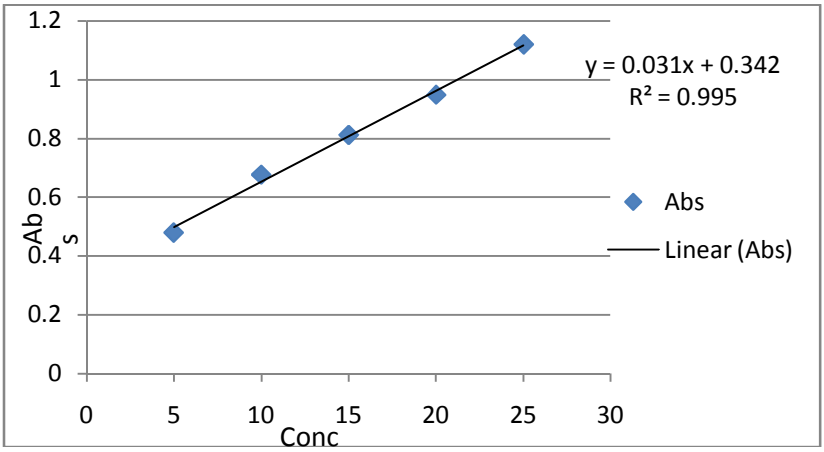

Figure 3: Linearity of Lurasidone Hydrochloride

Area Under Curve Method :

In the Experimental conditions described, the graph obtained for the Area Under Curve (AUC) spectra showed linear relationship (Figure 4). Regression analysis was made for the slope, intercept and correlation values. The range was found to be 5-25µm/ml for the Area Under Curve UV spectrophotometric analysis.

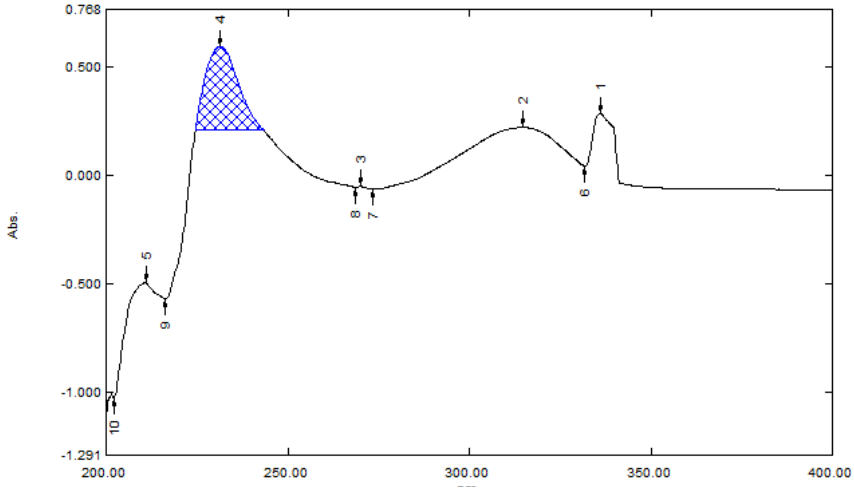

Figure 4: Area Under Curve of Lurasidone Hydrochloride

Table 3: Spectroscopic parameters.

Parameter	AUC
Wavelength Range (nm)	200 – 400
Concentration Range (µm/ml)	5-25
Regression Equation	y = 0.031x-0.342
Slope (m)	0.031
Intercept (c)	0.342
Correlation Coefficient (r^2)	0.9954

CONCLUSION

The simple and economic UV spectrophotometric AUC methods have been developed for the determination of Lurasidone Hydrochloride. Because of cost–effective and minimal maintenance, the present UV spectrophotometric methods can be preferred at small scale industries and successfully applied and suggested for the qualitative analysis of Lurasidone Hydrochloridein pharmaceutical formulations for QC, where economy and time are essential and to assure therapeutic efficacy. The results show the UV spectrophotometric method was found to be accurate, precise and sensitive.

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