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ESTIMATION OF RISPERIDONE IN TABLET DOSAGE FORM USING UV SPECTROPHOTOMETRIC METHOD

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ABSTRACT

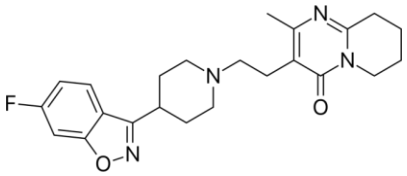
A simple, sensitive, specific, spectrophotometric method developed for the detection of Risperidone in bulk drug and Pharmaceutical formulation. The optimum conditions for the analysis of the drug were established. The λ max of the Risperidone was found to be 280 nm. The method shows high sensitivity with linearity 2 to 6µ g/ml. The lower limit of detection and the limit of quantification was found to be 1.012 and 3.036 respectively. All the calibration curves shows a linear relationship between the absorbance and concentration and coefficient correlation was higher than 0.99. The regression of the curve was Y = 0.039x - 0.002. Precision of the method was found to be 2.0325 ± 0.044 against the label claim of 2mg. The percentage recovery was found to be 102 ± 0.188. The sample solution was stable up to 2 hours. The proposed method will be suitable for the analysis of RIS in bulk and pharmaceutical formulation)

KEYWORDS: *Risperidone, Spectroscopy, Regression, λ max.*

INTRODUCTION

Risperidone is belonging to the chemical class of Benzisoxazole derivatives and chemically It is 4-(2-(4-(6-Flurobenzo[d]isoxazd-3yl]1-piperidyl]ethyl]-3-methyl-2,6 diazabicyclodeca-1,3-dien-5-one with molecular formula C23 H27 FN4O2 was presented in RIisperidone is an antipsychotic agent, which acts through selective antagonism of serotonin 5HT2, dopamine D2 receptors, used in the treatment of schizophrenia and other psychoses. It is mostly metabolized by alicyclic hydroxylation and oxidative N- dealkylation. An ideal stability

indicating method is one that quantifies the drug and also resolves its degradation products . Risperidone is soluble in 0.1N HCL and methanol and insoluble in sodium hydroxide and acetonitrile. The λ max was found to be at 280nm.



Structure of Risperidone

REAGENTS AND MATERIALS

Risperidone working Standard and Sample tablet; Respidon marketed tablets were procured from market; Methanol, Conc. HCl and Distilled water were used; UV/Vis double beam spectrophotometer, weighing balance, ultra sonicator were used for experimental purpose.

Experimental Work

The Objective of this Experiment was to enhance the solubility and optimize the assay method for the drug risperidone based on the literature survey was made.

Method Development

Preliminary Studies- As a starting point for the method development following preliminary studies is performed for the sample.

Solubility test

Table 1.

Drug	Description	Solvent Used	Result
RISPERIDONE	Weigh accurately 10 mg of sample intoa test tube and add the solvent place a lid and shake well if necessary sonicatefor 10 min	Methanol	Very Slightly Sol
		0.1M HCl	Slightly Sol
		50:50	Slightly Sol
		20:80	Slightly Sol
		30:70	Slightly Sol
		40:60	Freely Sol

- Preparation of methanol: 0.1N HCl (40:60% v/v) solution (Diluent): Methanol : 0.1N HCl (40:60 %v/v) was accurately weighed and transferred into a 100 ml volumetric flask.

Dissolved in a small quantity of distilled water and later volume was made up to 100 ml using distilled water.

- Preparation of stock solution (100 µg/ml):Standard stock solution of Risperidone was prepared by dissolving accurately weighed 10 mg of Risperidone in diluent in a 100 ml volumetric flask to give a concentration of 100 µg/ml. Sonicate the solution for 10 min and volume was made up to 100 ml with diluent.
- Preparation of working standard solution:From the stock solution, distilled water where the beer's law was obeyed.
- Preparation of sample stock solution:

Twenty tablets were weighed and powdered. Each tablet with a content of risperidone equivalent to 15 mg was transferred to a 100 ml volumetric flask and dissolved in diluent. Sonicate the solution for 10 min and volume was made up to 100 ml with diluent.

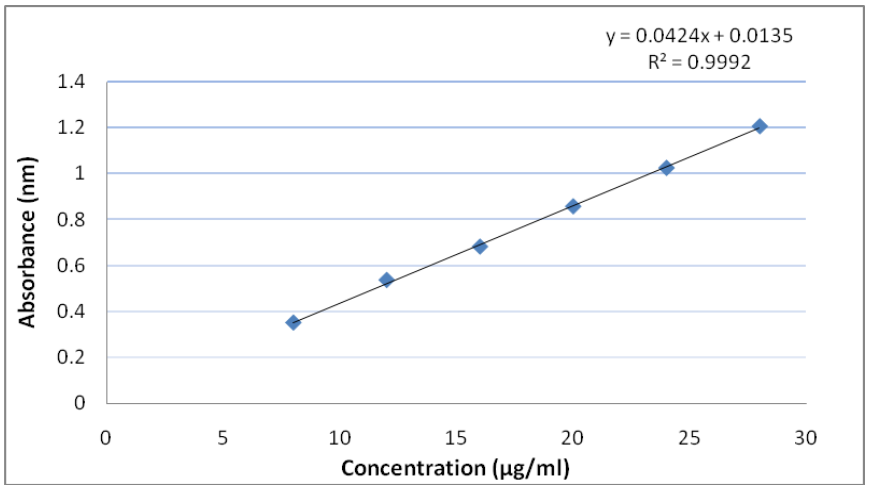
RESULTS AND DISCUSSION

Selection of wavelength by UV-Spectroscopy: The working standard solution, 100 µg/ml of risperidone was scanned in the wavelength range of 400-200 nm against the reagent blank to obtain the absorption maxima using UV-visible Spectrophotometer. The spectrum of drugs obtained is shown in Figure 5.1. Peak absorbance was obtained at 238 nm (λmax).

Calibration curve construction: The standard solution of risperidone was subsequently diluted with distilled water to obtain a series of dilutions containing 8, 12, 16, 20, 24 and 28 µg/ml. The absorbance of these solutions was measured using UV-visible Spectrophotometer at 238 nm against reagent blank. The concentrations of risperidone and the corresponding absorbances are given in Table 5.2. The standard graph for estimation of risperidone was plotted and is shown in Figure 5.2. The value of correlation coefficient (r) for the curve was calculated.

Table 2.

Concentration (µg/ml)	Absorbance (nm)
8	0.350
12	0.536
16	0.682
20	0.858
24	1.026
28	1.208



Calibration curve of risperidone

Method Validation

Accuracy:Accuracy test was performed at three different concentration levels of 50%,100%,150% i.e. 14, 28, 42 µg/ml solutions for UV with three replicates at each level in which the amount of sample was kept constant i.e., 28 µg/ml in UV. The percentage recovery is calculated for all the 9 readings were found to be within the limits as per ICH guidelines.

Table 3.

Concentration (µg/ml)	Amount Added		Amount Found	% Recovery
	A	B		
50%	14	28	42	95.69%
	14	28	42	97.06%
	14	28	42	97.35%
100%	28	28	56	96.28%
	28	28	56	96.54%
	28	28	56	96.54%
150%	42	28	70	96.13%
	42	28	70	96.37%
	42	28	70	96.29%

Precision: The precision of the method was demonstrated by intra-day and inter-day variation studies. In the inter-day variation study, the solutions of same concentration (20 µg/ml) were prepared and analyzed twice, for two consecutive days, and the absorbances were recorded (table 5.3). In the intra-day variation study, five different solutions of the same concentration (20 µg/ml) were prepared and analyzed thrice in a day (morning, afternoon, and evening) (table 5.4). The resultwas indicated by % RSD.

Table 4: (Interday Precision).

Concentration (µg/ml)	Absorbance (Day 1)	Absorbance (Day 2)
20	0.826	0.828
20	0.827	0.821
20	0.826	0.826
20	0.821	0.823
20	0.822	0.829
20	0.824	0.824
Average	**0.824**	**0.825**
SD	**0.002422**	**0.003061**
%RSD	**0.27%**	**0.37%**
Avg %RSD	**0.32%**	

Table 5: (Intraday Precision).

Concentration (µg/ml)	Absorbance 1	Absorbance 2	Absorbance 3
20	0.829	0.828	0.826
20	0.828	0.821	0.827
20	0.821	0.826	0.826
20	0.824	0.823	0.821
20	0.827	0.829	0.822
20	0.825	0.824	0.829
Average	**0.825**	**0.825**	**0.825**
SD	**0.002944**	**0.003061**	**0.003061**
%RSD	**0.35%**	**0.37%**	**0.37%**
Avg %RSD	**0.36%**		

Determination of limit of detection (LOD) and limit of quantification (LOQ):LOD and LOQ can be determined by the method as per ICH guidelines. The method used in this project is based on standard deviation of response and the slope of calibration curve. The limit of detection was found to be 0.53µg/ml.

The limit of quantification was found to be 1.62µg/ml.

Specificity: Results of Specificity studies shows no interference of excipients

Assay of marketed formulation (Respidon)

The sample stock solution was diluted with the solvent to the solution of concentration 28 µg/ml. The absorbance was measured against the blank diluents. The readings were taken in triplicate.

Table 6: Assay of Risperidone formulation(respidon).

Absorbance of sample solution		
S. No	**Concentration**	**Absorbance**
1	28	1.207
2	28	1.205
3	28	1.209
Average: 1.207		

Table 7: Summary of validation parameters.

Parameters	Results Obtained	Accepted Limits
ʎ max	238 nm	-
Linearity Range	8-28 µg/ml	-
Linearity(r^2)	0.9992	0.999-1
%RSD (intraday)	0.36	NMT 2.0
%RSD (inter day)	0.32	NMT 2.0
Accuracy (%)	95.69-97.35	-
LOD	0.53 µg/ml	- -
LOQ	1.62 µg/ml	-
Assay	99.80 %	99.02% -101.68%
Specificity	Specific	-

DISCUSSION

From the reported literature, there were few methods established for the determination of risperidone by uv-spectroscopy.

It was concluded that there was no method reported for the estimation of risperidone by using 40:60 Methanol : 0.1N HCl as solvent, which promote to pursue the present work. The scope and objective of the present work is to develop a method and validate for the drugrisperidone.

The analysis was carried out at 238 nm for risperidone. The correlation coefficient was found to be significant. The drug risperidone showed linearity between 8-28 µg/ml. The method was validated by accuracy, precision, LOD and LOQ. Precision of the developed method was studied. The %RSD values for precision were found to be within the acceptable limit, which revealed that the developed method was precise. LOD and LOQ were within the limits.

CONCLUSION

A simple and fast UV spectrophotometric method was described for drug risperidone in pharmaceutical dosage form. The developed method was validated by testing its linearity, accuracy, precision, LOD, and LOQ. The developed method is simple, sensitive, rapid, linear

and precise. Hence it can be used for the routine laboratory analysis of risperidone in individual dosage forms.

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