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First Order Derivative Spectrophotometric Method Develop and Validate for Estimation of Bifonazole in Bulk Drug and Pharmaceutical Formulation.

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Subject: Analytical chemistry

Abstract

A simple, rapid and sensitive reproducible First order UV Spectrophotometric method was developed for estimation of Bifonazole (BIF) in bulk drug and pharmaceutical formulation using double beam UV spectrophotometer. Ultraviolet Spectrophotometric analysis was carried out on a Shimadzu UV 1800 (Shimadzu, Japan) spectrophotometer, in a 1cm quartz cuvette. The method involved measurement of absorbance at wavelengths 223 nm. Beer's law obeyed in concentration range of 1 to 12 µg/ mL. The proposed method was applied successfully to the determination of Bifonazole in pharmaceutical formulation with good accuracy and precision.

Keyword: *Spectroscopy, First Order Derivative, Bifonazole, Validation*

Introduction

Bifonazole is chemically 1-[(*RS*)-(biphenyl-4-yl) phenyl methyl]-1*H*-imidazole belonging to imidazole derivatives and official in the European Pharmacopoeia [1]. Bifonazole is antifungal agent having broad spectrum of activity in vitro against dermatophytes, moulds, yeasts, dimorphic fungi and some Gram-positive bacteria and use as a standard for measuring antifungal activity of synthesize azole derivative [2,3]. Pharmaceutical formulations containing Bifonazole exist in the form of lotion, powder or cream[4]. So far, the compound mentioned above was determined using various techniques, exemplified by electrochemical[5], chromatographic [6,7] Spectrophotometric [8] individual and combination with other drug. However, there are a limited number of published papers related to UV spectrophotometry [9]. In the present study first order derivative method for a direct determination of Bifonazole in bulk drug and pharmaceutical formulation like cream carried out. Derivative spectrophotometry is a useful technique for qualitative and quantitative analysis [10,11] and helps in reducing the effects of spectral background interferences. Derivative spectroscopy very useful in qualitative analysis, either for characterizing Materials or for identification Derivative spectra can be obtained by optical, electronic, or mathematical methods. The advantages of the mathematical techniques are that derivative spectra may be easily calculated and recalculated with different parameters, and smoothing techniques may be used to improve the signal-to-noise ratio. From Fig. II clearly indicate the common, unwanted effect in spectroscopy is baseline shift. This may arise either from instrument (lamp or detector instabilities) or sample handling (cuvette repositioning) effects, using the first derivative spectra always eliminates such baseline shifts and improves the accuracy of quantification [12, 13].

Material and Method

Instrumentation

Spectrophotometric measurements were performed on Shimadzu 1800 spectrophotometer with 1.0 cm quartz cuvettes.

Instrumental conditions were: wavelength range 200- 600 nm; scan rate 1000 nm/min; slit 1.0 nm. All weighing were done on single pan balance (Shimadzu).

Reagents and Chemical

Bifonazole procured from Enqubeethecal Pvt Ltd Mumbai. All other reagents were of analytical grade of purity (Merck). Glass double distilled water was used throughout the experiment. Pharmaceutical formulation cream was purchased from local market each containing 1 mg of BIF.

Standard solution

Stock solution of Bifonazole (150 mg/ml) was prepared in 0.1 M HCl. Aliquots of 0.25, 0.50, 1.00, 1.50 and 2.50 ml of this solution were transferred into 25-ml volumetric flasks and diluted with 0.1 M HCl to 25 ml. The spectra were recorded using 0.1 M HCl as a blank. The Bifonazole has the absorbance maxima of derivative spectra at 223 nm.

Analysis of Bifonazole cream

The amount of the cream containing approximately 1.0 mg Bifonazole was transferred into a 20 ml 0.1 M HCl in 25-ml volumetric flask. After homogenization by a warm water bath (10 min), the sample was cooled to ambient temperature and the volume adjusted to 25 ml with 0.1 M HCl. After filtration 1.0 ml of the solution was diluted to 25 ml with 0.1 M HCl. The effects of the acidity and temperature on Bifonazole were examined spectrophotometrically. Applying the same procedure as that used for bulk drug for the analysis of the cream, no changes in the absorption spectra were detected and absorbance maxima of derivative spectra at 223 nm were observed.

First Order Derivative Method

From the spectra the detection wavelength selected for analysis was 223 nm The calibration curve was prepared in the concentration range of 1-12 µg/ mL at 223 nm. By using the calibration curve, the concentration of the sample solution was determined.

Result:

Method validation

The Method was validated as per ICH guidelines using different parameter.

Linearity:

The linearity was evaluated by analyzing different concentration of standard solution of BIF. The Beer Lambert's law was obeyed in the concentration range of 1 to 12 µg/ mL. The results obtained were tabulated and plotted a calibration curve of absorbance versus concentration. The slope of the calibration curve is determined by regression equation.

Limit of Detection and Limit of Quantitation:

LOD and LOQ were calculated from the data obtained by linearity studies. The slope of the linearity plot was determined. For each of the six replicate determinations, y intercept was calculated and the standard deviation of the y intercept was computed. From these values, the parameters Limit of Detection (LOD) and Limit of Quantitation and (LOQ) were determined on the basis of response and slope of the regression equation. The result was given Table I.

Precision:

Six replicate analyses of Cream by the proposed method were done. The results of the precision study indicate that the method is reliable. The intermediate precision (inter-day precision) of the method was also evaluated using two different analysts in different days in same laboratory. Results are shown in Table II and III.

Accuracy (Recovery studies)

Accuracy of the method was studied by recovery experiments. The recovery experiments were performed by adding known amounts of the drugs. The recovery was performed at three levels, 80%, 100% and 120% of the label claim of the tablet. The result shown in Table no. IV.

Discussion

The proposed methods for estimation of BIF in pharmaceutical dosage form were found to be accurate, simple and rapid. Hence it can be used for routine analysis of these drugs in pharmaceutical dosage forms. There was no interference from tablet excipients was observed in these methods. The values of % RSD and correlation of coefficient were found to be (% RSD 0.49-1.08) and correlation coefficient was 0.998 for BIF. The result of recovery studies for pharmaceutical formulation was found to be in the range of 99.44 - 100.50%. Values are reported in Table 4. It indicates that there is no interference due to excipients present in the formulation. It can be easily and conveniently adopted for routine quality control analysis. Both methods are accurate, simple, rapid, precise, reliable, sensitive, reproducible and economic and are validated as per ICH guidelines.

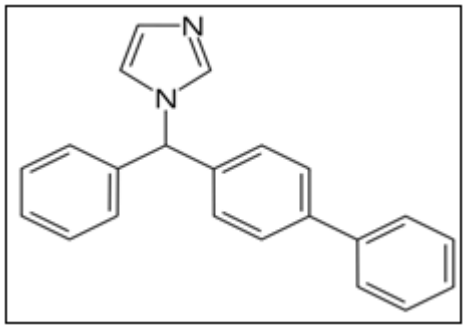

Fig. 1 Structure of Bifonazole

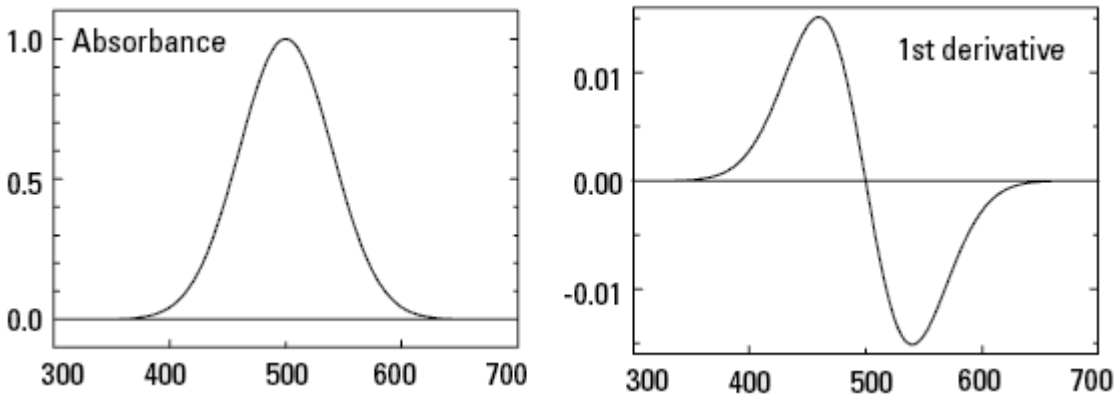

Fig. 2 Difference Absorbance and 1st order Derivative Spectra of Gaussian band

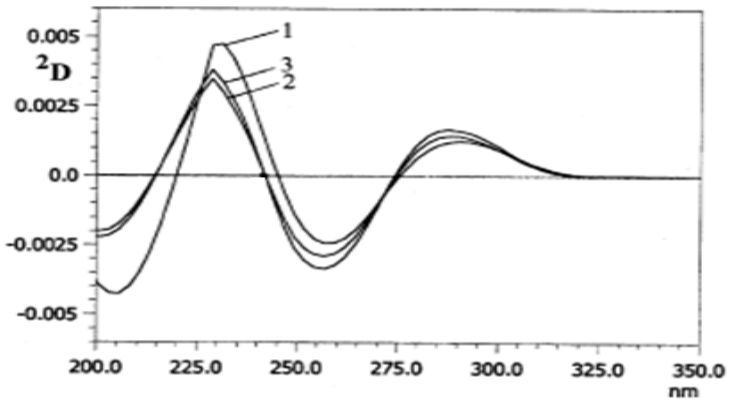

Fig. 3 First-order spectrum of Bifonazole

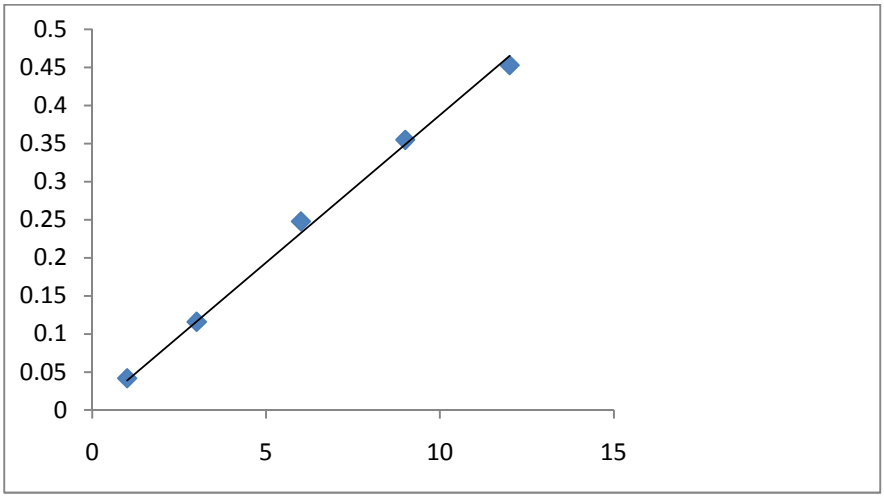

Fig. 4 Calibration curve for Bifonazole

Table 1 Optical Characteristics of Bifonazole

Parameters	**1st Order Derivative Method**
λmax (nm)	223 nm
Linearity (µg/ml)	C µg/mL
r^2 Value	0.999
a. Slope(m)	0.762
LOD (µg/ml)	0.3
LOQ (µg/ml)	1.2

Table 2 Intraday and Interdaydata of Cream formulation

Drug in mg	**Intraday precision %COV (n =5)**	**Interday precision %COV**		
		Day 1	**Day 2**	**Day 3**
1	0.46	0.388	0.276	0.156

Table 3 Results of Analysis of Cream Formulation.

Label Claim in mg	**Amount of drug estimated**	**%Label claim ±SD**	**Recovery % ±SD**
1 .00	1.00	100.00 ± 0.075	100.00

Table 4 Result of Pharmaceutical dosage form containing Bifonazole

Leval of % Recovery	Concentration Taken(µg/mL)	Concentration estimated (µg/mL) **(±SD)**	% Analytical recovery
80	1.8	1.79±0.024	99.44
100	2.0	1.98±0.025	99.00
120	2.2	2.21±0.021	100.45

Conclusion

The results of our study indicate that the proposed UV spectroscopic methods are simple, rapid, precise and accurate. The developed UV spectroscopic methods were found suitable for determination of BIF in bulk drug and in marketed Cream formulation without any interference from the excipients. Statistical analysis proves that, these methods are repeatable and selective for the analysis of BIF. It can therefore be concluded that use of these methods can save much time and money and it can be used in laboratories with accuracy.

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