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Original Article

SIMULTANEOUS DETERMINATION OF FLURBIPROFEN AND PANTOPRAZOLE IN BULK AND PHARMACEUTICAL DOSAGE FORM BY UV SPECTROPHOTOMETER

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ABSTRACT

Objective: A simple, rapid, precise and accurate spectrophotometric method has been developed for determination of Flurbiprofen and Pantoprazole by simultaneous equation method in combined dosage form

Methods: The 6.8 pH phosphate buffer was selected as solvent for developing spectral characteristics of both drugs. The method was validated for recovery studies.

Results: The λmax of Flubiprofen was found to be 230 nm and Pantoprazole was found to be 270 nm. The method obeyed Beer's law in the concentration range of 10-100 µg/ml for Flurbiprofen and 10-100 µg/ml for Pantoprazole. The percentage recovery of Flubiprofen was found to be 99.16 and Pantoprazole was found to be 99.46.

Conclusion: The proposed method was validated and can be used for analysis of combined tablet formulation containing Flurbiprofen and Pantoprazole.

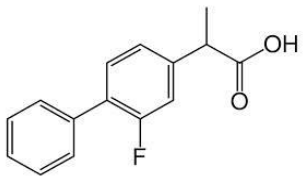
Keywords: Flurbiprofen, Pantoprazole, Simultaneous equation method, and Validation.

INTRODUCTION

Spectroscopy is the branch of science dealing with the study of Electro Magnetic Radiation with matter[1]. Analytical method validation is "the collection and evaluation of data,from the process design stage throughout production, which establishes scientific evidence that a process is capable of consistently delivering quality products[2].

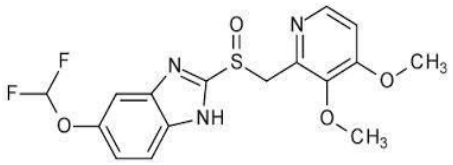
Flurbiprofen is a member of the phenylalkanoic acid derivative family of non-steroidal anti-inflammatory drugs (NSAIDs) used to treat the inflammation and pain of arthritis. Flurbiprofen is also used as an active ingredient in some kinds of throat lozenges (Strepsils Intensive) Chemically it is (*RS*)-2-(2-fluorobiphenyl-4-yl) propanoic acid[4].

Structure of Flubiprofen



Pantoprazole; 5-(difluoro methoxy)-2-[[(3, 4 dimethoxy-2-pyridinyl) methyl] sulfinyl]-1H-benzimidazole, is used asantiulcer drug[3].

Structure of Pantoprazole



Literature survey reveals that there are UV and HPLC methods reported for the estimation of pantoprazole in pharmaceutical formulations.

The review of the literature revealed that no method is yet reported for the simultaneous estimation of both the drugs in combined dosage forms. This paper describes two simple, rapid, accurate, reproducible and economical methods for the simultaneous estimation of flurbiprofen and pantoprazole in tablet formulations using simultaneous equation methods.

MATERIALS AND METHODS

Materials

Spectral runs were made on a Shimadzu UV-Visible spectrophotometer with spectral bandwidth of 0.5 nm and wavelength accuracy of ± 0.3 nm with automatic wavelength corrections with a pair of 10 mm quartz cells.

Selection of common solvent

The 6.8 pH phosphate buffer were selected as a common solvent for developing spectral characteristics of both drugs. The selection was made after assessing the solubility of both the drugs in different solvents.

Preparation of standard stock solution

Standard stock solutions (100 µg /ml) of Flurbiprofen and Pantoprazole were prepared by dissolving separately 10mg of each drug in ethanol and volume was added made up to 100 ml with 6.8 pH phosphate buffer. The working standard solutions of these drugs were obtained by dilution of the respective stock solution with 6.8 pH phosphate buffer.

Analysis of pharmaceutical dosage form

Twenty tablets were weighed accurately; average weight was determined and then ground to a fine powder. A quantity equivalent to 100 mg of Flurbiprofen and 40 mg of Pantoprazole were transferred to a 100 mL volumetric flask. The contents were ultrasonication for 10 min with 6.8 pH phosphate buffer made to volume and filtered through Whatmann filter paper No.41. The solution was further diluted with 6.8 pH phosphate buffer to give concentrations of 10 mcg/mL of Flurbiprofen and Pantoprazole

respectively. Absorbance of these solutions was measured at 230 nm and 270 nm as A1 and A2 respectively and concentrations of these two drugs in the sample were calculated using equations.

Simultaneous equation method

For the simultaneous equation method, 230 nm and 270 nm were selected as the two sampling wavelengths for Flurbiprofen and Pantoprazole respectively. The Flurbiprofen and Pantoprazole exhibited linearity in the concentration range of 10-100 µg/ml and 10-1000 µg/ml at their respective selected wavelengths respectively. Coefficients of correlation were found to be 0.999 and 0.996 for Flurbiprofen and Pantoprazole respectively. The optical characteristic values for the calibration curves are presented in **Table 1**. For simultaneous estimation of Flurbiprofen and Pantoprazole, mixed standards containing Flurbiprofen and Pantoprazole in a concentration ratio of 1:4 µg/ml each were prepared by appropriate dilution of the standard stock solutions with distilled water. The absorbance of the mixed standard solutions were measured at the selected wavelengths. The two equations were constructed based upon the fact that at λ1 and λ2 the absorbance of the mixture is the sum of individual absorbances of Flurbiprofen and Pantoprazole.

$$\text{At } \lambda 1,\ A1 = ax1bcx + ay1bcy \ldots\ldots (1)$$

$$\text{At } \lambda 2,\ A2 = ax2bcx + ay\ 2bcy \ldots\ldots (2)$$

Where, A1 and A2 are absorbance of mixed standard at 230 nm and 270 nm respectively. λ1 and λ2 are wavelengths of Flurbiprofen and Pantoprazole respectively, ax1 and ax2 are absorptivity of Flurbiprofen at λ1 and λ2, ay1 and ay2 are absorptivity of Pantoprazole at λ1 and λ2 respectively. cx and cy are concentration of Flurbiprofen and Pantoprazole respectively.

Accuracy

The accuracy of the method was established by using recovery experiments i. e. by external dilution method. The known amount of standard was added at three different levels of 80%, 100% and 120% of sample. The percentage recoveries were calculated from calibration curve. The data is summarised in table 3.

Precision

The precision of analytical procedure expresses the closeness of agreement (degree of scatter) between a series of measurement obtained from multiple sampling of the same homogenous sample under the prescribed condition. Precision was determined by repeatability (intra-day) and intermediate precision (inter-day). Repeatability was evaluated by 3 determinations of 3 different concentrations during the same day. Intermediate precision was determined during 3 different days. Precision (intra-day and inter-day) were expressed as relative standard deviation.

Linearity

The linearity of an analytical procedure is its ability to obtain test results which are directly proportional to the concentration of analyte in the sample. Calibration curve was constructed by plotting absorbance versus concentration which showed linearity over the concentration range of 10-100µg/ml as shown in figure 1 &2.

Detection and quantification limits

Limit of detection(LOD)

The limit of detection of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected it was calculated using the following formula

$$LOD = 3.3\sigma/S$$

Where, = the standard deviation of the response, S = the slope of the calibration curve (of the analyte)

Limit of quantification (LOQ)

The limit of quantification of an individual analytical procedure is the lowest amount of analyte in a sample which can be quantitatively determined. It was calculated using the following formula

$$LOQ = 10\sigma/ S$$

Where σ, =the standard deviation of the response, S=the slope of the calibration curve (of the analyte).

RESULTS AND DISCUSSION

Under the experimental conditions described, calibration curve, assay of tablets and recovery studies were performed. The linearity of Flubiprofen was found to be 10-100mcg/ml as shown in **Figure 1** and for Pantoprazole linearity was found to be 10-100msg/ml as shown in **Figure 2**.

λ max (nm) of Flubiprofen was found to be 230 nm and for Pantoprazole 270 nm. The developed methods were validated as per ICH guidelines for linearity, repeatability, LOD, LOQ in 6.8pH Buffer and 0.1N HCl [5] as shown in **Table 1**. The mean % recovery of Flurbiprofen and Pantoprazole were found to be 99.16 % and 99.47% respectively by simultaneous equation method as shown in **Table2**. The mean % content of Flurbiprofen and Pantoprazole in tablet formulation by the simultaneous equation method was found to be 99.08% and 99.9% respectively as shown in **Table3.**

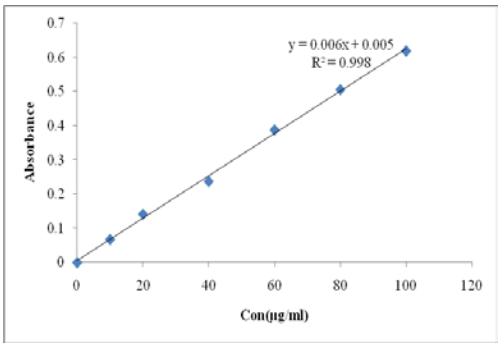


Fig. 1: Calibration Curve of Flubiprofen in 6.8 Buffer

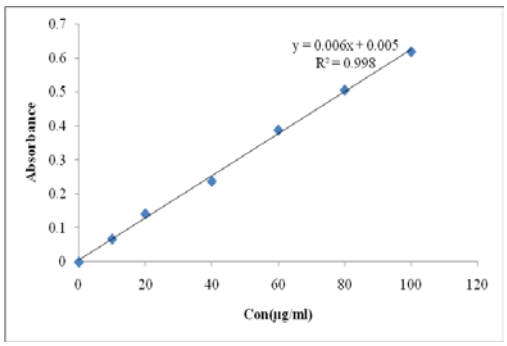


Fig. 2: Calibration Curve of Pantoprazole in 6.8 Buffer

Table1: Optical Characteristics and Validation Parameters of Flurbiprofen and Pantoprazole in 6.8pH phosphate buffer

Parameter	Flurbiprofen	Pantoprazole
λ max (nm)	230	270
Precision	0.122	0.136
LOD (µg/ml)	4.2	3.7
LOQ (µg/ml)	9.3	8.4
Regression equation	y=0.007x+0.022(R^2=0.998)	y=0.006x+0.005(R^2=0.998)

Optical Characteristics and Validation Parameters of Flurbiprofen and Pantoprazole in 0.1 HCl

Parameter	Flurbiprofen	Pantoprazole
λ max (nm)	230	270
Linearity	10-30	10-80
Precision	0.122	0.136
LOD (µg/ml)	4.2	3.7
LOQ (µg/ml)	9.3	8.4
Regression equation	y=0.03x+0.001(R^2=0.999)	y=0.007x+0.022(R^2=0.990)

Table 2: Analysis of Pharmaceutical Dosage Form (Tablet form)

Drug	Label cliam(mg)	Amount found (%)	S. D.
Flurbiprofen	100	99.16	0.12
Pantoprazole	40	99.46	0.19

Table3: Recovery data of Flurbiprofen and Pantoprazole

Level of recovery (%)	Recovery of Flurbiprofen	Recovery of Pantoprazole	S. D. Flurbiprofen	S. D. Pantoprazole
80	98.25	100.08	0.91	0.31
100	99.98	99.76	0.43	0.65
120	99.03	99.86	0.52	0.98

CONCLUSION

A simple, rapid, precise and accurate spectrophotometric method has been developed for simultaneous estimation of Flurbiprofen and Pantoprazole by using simultaneous equation method. The standard deviation and RSD were found to be low, indicating high degree of precision of the methods. The % recovery was found to be occurred within a range of 98-102% indicating high degree of accuracy of the proposed method. The developed methods can be employed for the routine estimation of Flurbiprofen and Pantoprazole in both bulk and tablet dosage form.

CONFLICT OF INTERESTS

Declared None

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REFERENCES

1. Introduction to Spectroscopy-www. wikipediacomweb dictionary.
2. Ermer & Miller-Method validation in Pharmaceutical analysis. p. 21-171.
3. U Swati, *et al.* Estimation of Domperidone and Pantoprazole-Scholars Reasearch library. 2012;4(4):1517-21.
4. Mamatha Thirunagari, Solubility Enhancement studies of Flubiprofen using different Solubilization techniques. IJPPS vol supply4. 2012;4.
5. Jigar Pandya, *et al*. Development and validation of differential spectrophotometric method for pantoprazole in tablet dosage. J of Pharm Sci and Bioscientific Res vol. 2(1).
6. Indian Pharmacopoeia, edition volI&II. 1996.
7. British Pharmacopoeia, edition. 2007.
8. British Pharmacopoeia, Vol. London: Her Majesty's Stationary Office. 2008;1.
9. Pharmacopoeia, III. The European edition. 1997
10. Raju M S, *et al.* Spectrophotometric determination of Pantoprazole by Precipitation reactions and by HPLC. Asian J Chemistry 2004;16(2).