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Simple Spectrophotometric determination of *Tegaserod Maleate* in Pharmaceutical dosage forms

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Abstract

Plan: *An analytical method for the estimation of Tegaserod Maleate in bulk drugs and pharmaceutical dosage forms is described.*

Prologue: *Tegaserod Maleate is the first selective serotonin 5-HT4 receptor partial agonist to improve symptoms of constipation-predominant Irritable Bowel syndrome. The present study aims at the development of simple Spectrophotometric method for the estimation of Tegaserod in dosage forms.*

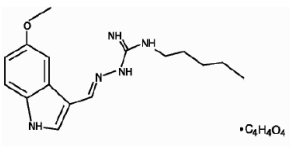
Methodology*: The developed method is based on the formation of a purple coloured complex due to the reaction of Tegaserod Maleate with p-Dimethylaminobenzaldehyde reagent, which gave a maximum absorbance at 515nm. Beer's law is obeyed over the concentration range of 5-50µg/ml. All the variables were studied to optimize the reaction conditions.*

Outcome*: The proposed method is simple, fast, accurate and economical and can be used for the routine analysis of Tegaserod in dosage forms.*

Keywords*: Tegaserod Maleate, p-Dimethylaminobenzaldehyde, Spectrophotometric method*

1. Introduction

Tegaserod maleate is chemically known as 2-[(5-Methoxy-1H-indole-3-yl) methylene Npentylhydrazinecaroximidamide[1,2]. Tegaserod Maleate is the first selective serotonin 5-HT4 receptor partial agonist to improve symptoms of constipation-predominant Irritable Bowel syndrome[3]. Literature survey reveals that the drug is not official in any pharmacopoeia[4].



Tegaserod Maleate

2. Experimental

2.1 Instrument: Jasco V-530 Spectrophotometer with 1cm quartz cells were used for the studies.

2.2. Chemical reagent: Standard drug solution: 1mg/ml of Tegaserod Maleate in dehydrated alcohol was used P- Dimethylaminobenzaldehyde (p-DMAB) reagent: 1 gm of p-DMAB dissolved in 30ml of dehydrated alcohol, then added 180 ml of n-butanol and 30ml of hydrochloric acid[5].

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2.2.1. Development of coloured complex

0.1 ml of standard solution (100µg/ml) was taken in a test tube, 1 ml of p-DMAB reagent was added and heated on a boiling water bath for 4 mins, cooled and then transferred to a 10ml standard flask and made up to volume with n-butanol.

2.2.2. Preparation of reagent blank

0.1 ml of dehydrated alcohol was taken in a test tube, 1ml of p-DMAB reagent was added and heated on a boiling water bath for 4 mins, cooled and then transferred to a 10ml standard flask and made upto volume with n-butanol.

2.3 Development of coloured complex

Accurately pipetted out 0.05, 0.1, 0.15, 0.2, 0.25, 0.3, 0.35, 0.4, 0.45 &0.5 ml of Tegaserod standard solution into ten test tubes respectively. To each test tube added 1ml of p-DMAB and heated on a boiling water bath at 100^{o}C for 4 mins. The solutions were cooled and then transferred to 10 ml volumetric flasks and finally made up to volume with n-Butanol. The absorbance was measured at 515 nm against reagent blank and the standard calibration curve was prepared. The results are furnished in table 1.

Table 1 Data for Beer's law plot for Tegaserod Maleate

Concentration(µg/ml)	*Absorbance at 515 nm*
5	0.0497
10	0.0989
15	0.1476
20	0.2044
25	0.2499
30	0.3045
35	0.3495
40	0.4066
45	0.4550
50	0.5330

2.4 Standardisation of method

2.4.1 Optimization of volume of p-DMAB reagent

0.5,1,2,3 ml of p-DMAB reagent was treated with 0.1, 0.3, 0.5 ml of Tegaserod standard solution respectively, heated on a boiling water for 4 mins, cooled and then transferred to 10 ml volumetric flasks and made up to volume with n-butanol.The absorbance was measured at 515nm using reagent blank.

2.4.2 Standardisation of heating time

Five aliquots each of 0.1, 0.3, 0.5 ml of Tegaserod standard solution was treated with 1ml of p-DMAB reagent and heated on a boiling water bath for 1,2,3,4 and 5 mins respectively, cooled and then transferred to 10 ml volumetric flasks and made up to volume with n-butanol. The absorbance was measured at 515 nm using reagent blank.

2.5 Stability of the complex

0.1,0.3,0.5 ml of Tegaserod standard solution was used for the development of coloured complex and stability of these complexes were studied over a period of 1 hour at 5 min intervals.

2.6. Estimation of Tegaserod in dosage forms

2.6.1 Extraction of Tegaserod from tablets

Twenty tablets were accurately weighed and finely powdered in a glass mortar. A weight equivalent to 25 mg was accurately weighed and transferred to a stoppered test tube and 5 ml of dehydrated alcohol was added and swirled gently for 10 mins. The solution was then transferred to a 25 ml standard flask through a whatmann filter paper. The residue was further extracted with dehydrated alcohol and transferred to the standard flask through the filter paper and the final volume was made up to 25 ml with dehydrated alcohol.

2.6.2 Development of colour

Accurately pipetted out 0.1, 0.25, 0.5 ml of the above solution into three test tubes and the colour was developed as mentioned in section 2.3.The absorbance was measured at 515 nm against reagent blank and the content of Tegaserod Maleate per tablet was determined.

3. Results and Discussion

3.1 Spectral Characteristics

Absorption spectrum of the purple coloured complex is shown in Fig.1 with a maximum absorbance at 515 nm. The absorbance data reveals that the complex was relatively more stable for the first 30 mins.

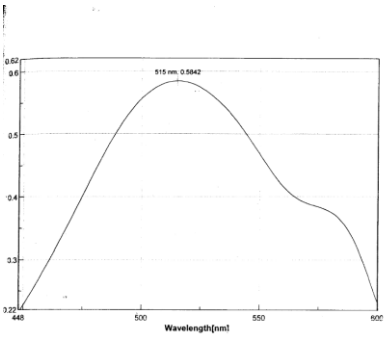

Fig.1

3.2 Statistical analysis of Beer's law plot

A calibration graph (Fig 2) was obtained by plotting concentration against absorbance measured at 515 nm and linearity was obtained in the region of 5-50µg/ml. The data for Beer's law plot was used to derive regression equation of the absorbance (Y) on the concentration (X) as Y=0.01013X – 0.00173. The correlation equation was obtained as 0.999877. The molar absorptivity value in the Beer's law region was found to be 4.2025 x 10^3 L mol $^{-1}$ cm $^{-1}$.

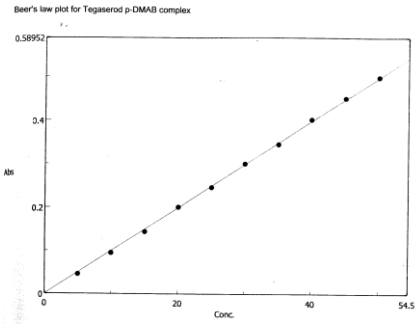

Fig.2 calibration graph

3.3 Optimization of variables

The volume of p-DMAB reagent required to produce maximum and stable absorbance was found to be 1ml. Heating on a boiling water bath for 4mins was found to give maximum absorbance.

3.4 Application to dosage forms

The proposed method was successfully applied to the determination of Tegaserod Maleate in commercial tablets. The applicability of the proposed method for the assay of Tegaserod Maleate in formulations was examined by analyzing its formulation and results are tabulated in table 2.

Concentration of Tegaserod(µg/ml)	*Absorbance at 515nm (Standard)*	*Absorbance at 515 nm (Sample)*	*% Label claim*	*Active content per tablet(mg)*	*Average content per tablet (mg)*
10	0.0989	0.0988	99.89	5.9934	
25	0.2499	0.2489	99.59	5.9754	5.9848
50	0.5033	0.5021	99.76	5.9856	

4. Conclusion

In the present study, a simple Spectrophotometric method is described for the determination of Tegaserod Maleate in dosage forms. The method is simple, sensitive, less time consuming and reproducible and hence the proposed method can be used for the routine analysis of Tegaserod Maleate in bulk drug and pharmaceutical dosage forms.

Acknowledgement

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