Original Article

Spectrophotometric estimation of solifenacin succinate in tablet formulations

Abstract

Aim: The aim of this study is to develop a simple, sensitive, rapid, accurate, and precise spectrophotometric method for the estimation of solifenacin succinate in tablet dosage forms. **Materials and Methods:** For methods I and II, in a series of 10 ml volumetric flasks, aliquots of standard drug solution (100 μg/ml) in double distilled water were transferred and diluted with the same so as to give several dilutions in the concentration ranges of 10 – 60 μg/ml and 10 – 60 μg/ml, respectively, of solifenacin succinate. To 5 ml of each dilution taken in a separating funnel, (5 ml of bromo thymol blue for method I and 5 ml of bromo phenol blue for method II) reagent and 5 ml of chloroform were added. The reaction mixture was shaken gently for five minutes and allowed to stand so as to separate the aqueous and chloroform layers. The absorbance maxima were measured at 415.6 nm and 412 nm for methods I and II, respectively. **Results:** The recovery studies were found close to 100%, which indicates the accuracy and precision of the proposed methods. Statistical analysis was carried out, the results of which were found to be satisfactory. Standard deviation values were found to be low and that indicated the reproducibility of the proposed methods. **Conclusion:** The results indicated that both methods could be used for the routine estimation of solifenacin succinate from tablet formulations.

Key words: Bromo phenol blue, bromo thymol blue, solifenacin succinate, spectrophotometric

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INTRODUCTION

Solifenacin succinate is an orally administered urinary antispasmodic anticholinergic drug. The chemical name of Solifenacin succinate is 1-azabicyclo [2.2.2] octan-8-yl (1s)-1-phenyl-3,4-dihydro-1h-isoquinoline-2-carboxylate butanedioic acid.[1] Solifenacin is a competitive muscarinic acetylcholine receptor antagonist. The binding of acetylcholine to these receptors, particularly the M_3 receptor subtype, plays a critical role in the contraction of the smooth muscle. By preventing the binding of acetylcholine to these receptors, solifenacin reduces the smooth muscle tone in the bladder, allowing the bladder to retain larger volumes of urine and reducing the number of micturition, urgency, and incontinence episodes.[2,3] A literature survey reveals one semi-micro high-performance liquid chromatography (HPLC) method[4] and one simultaneous liquid chromatography electrospray ionization tandem mass spectrometry (LC-ESI-MS / MS) method[5] for the determination of Solifenacin succinate in plasma. There are no spectrophotometric methods reported for the estimation of Solifenacin succinate in the pharmaceutical dosage form. Thus, efforts are being made to develop a fast, selective, and sensitive analytical method for the estimation of Solifenacin succinate in its tablet formulations. Solifenacin succinate is only available in the form of an oral tablet.

MATERIALS AND METHODS

Materials

Shimadzu UV 1700, a UV-Visible double beam spectrophotometer, with a

spectral band width of 1 nm, wavelength accuracy of ± 0.3 nm, and 1.0 cm matched quartz cells, was used for development of the analytical method. All the chemicals and reagents used were of analytical grade. Solifenacin succinate supplied by BePharm, Ltd. (China), was used as such, without further purification. Bromo thymol blue and Bromo phenol blue (Loba Chemie, Mumbai) reagents were prepared in double distilled water. All the reagents were extracted several times with chloroform so as to remove the chloroform-soluble impurities. The tablets of Solifenacin succinate were procured from a local pharmacy. BISPEC tab® 10 mg [Dr. Reddy's] and SOLITEN film-coated tab® 10 mg [Ranbaxy], were procured. A standard solution of Solifenacin succinate was prepared by dissolving 10 mg in 100 ml of double distilled water, to give a stock solution of concentration 100 µg/ml of the drug.

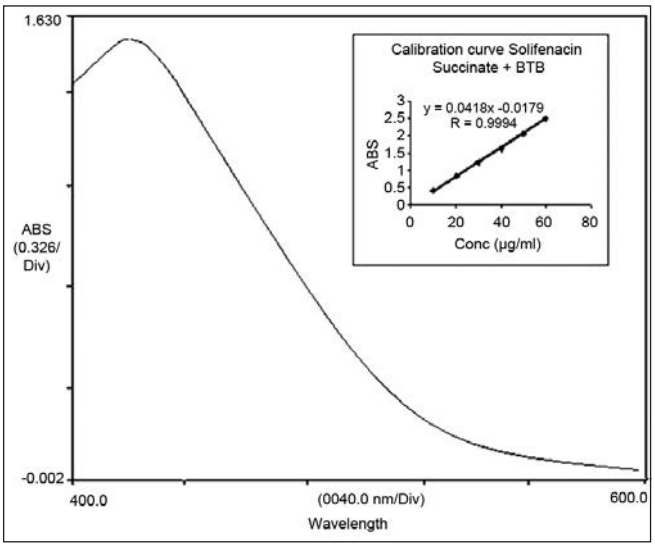

Figure 1: UV spectrum of Solifenacin succinate with bromo thymol blue reagent

Methods

Procedure for preparation of the calibration curve

For method I, in a series of 10 ml volumetric flasks, aliquots of the standard drug solution (100 µg/ml) in double distilled water were transferred and diluted with the same, so as to give several dilutions in the concentration range of 10 – 60 µg/ml of Solifenacin succinate. To 5 ml of each dilution, taken in a separating funnel, 5 ml of bromo thymol blue (0.3% w/v) reagent and 5 ml of chloroform were added. The reaction mixture was shaken gently for five minutes and allowed to stand, so as to separate the aqueous and chloroform layers. The chloroform layer was separated out and an absorbance maximum was measured against a reagent blank. The calibration curve was plotted [Figure 1] between the concentrations of Solifenacin succinate and the measured absorbance.

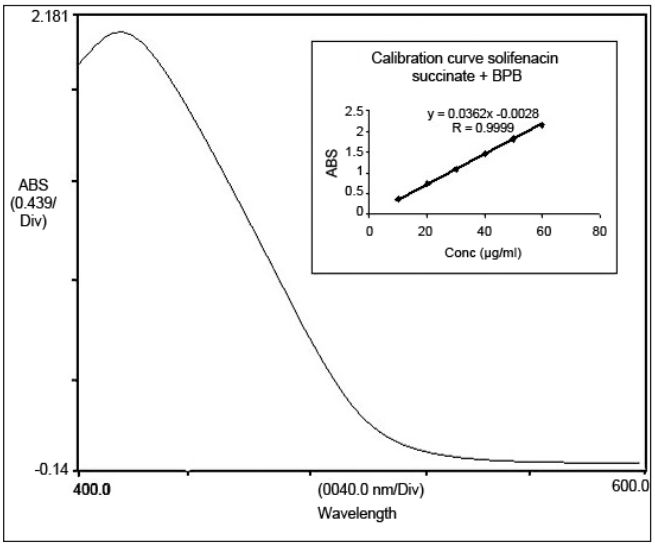

Figure 2: UV spectrum of Solifenacin succinate with bromo phenol blue reagent

For method II, in a series of 10 ml volumetric flasks, aliquots of the standard drug solution (100 µg /ml) in double distilled water were transferred and diluted with the same, so as to give several dilutions, in the concentration range of 10 – 60 µg/ml of Solifenacin succinate. To 5 ml of each dilution, taken in a separating funnel, 5 ml of bromo phenol blue reagent (0.3% w/v) and 5 ml of chloroform were added. The reaction mixture was shaken gently for five minutes and allowed to stand, so as to separate the aqueous and chloroform layers. The chloroform layer was separated out and an absorbance maximum was measured against a reagent blank. The calibration curve was plotted [Figure 2] between the concentrations of Solifenacin succinate and the measured absorbance. The spectral characteristics of Solifenacin succinate for method I and method II are given in Table 1.

Table 1: Spectral characteristics of Solifenacin succinate

Parameters	Method I	Method II
λ max	415.6 nm	412 nm
Beer's law limit (µg/ml)	10 – 60 µg/ml	10 – 60 µg/ml
Regression equation*A + bc	y = 0.0418x - 0.0179	y = 0.0362x + 0.0028
Slope (b)	0.0418	0.0362
Intercept (a)	- 0.0179	+ 0.0028
Correlation coefficient (r)	0.9994	0.9999
Molar Absorptivity*(L/mol/cm)	1.98×10^{10}	1.73×10^{10}

y = a + bc, where c is the concentration in µg/ml, y is the absorbance unit of six replicate samples, and b is the slope of the line equation; *Average of nine determinations