



Simultaneous estimation of Nebivolol and S-Amlodipine in tablets by UV-Spectrophotometry

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Abstract

The present work describes a simple first derivative spectrophotometric method for simultaneous estimation of nebivolol and s-amlodipine in tablets. The wavelengths selected for analysis were 242.0 nm and 290.0 nm for s-amlodipine and nebivolol, respectively. Both nebivolol and s-amlodipine were found to obey Beer's law over the concentration range of 0-60 µg/ml at selected wavelengths. The proposed method was validated statistically and by recovery studies.

Keywords: Nebivolol (NEBI) and S-amloldipine(S-AMLO).

INTRODUCTION

Nebivolol (NEBI) is a synthetic antihypertensive agent. Chemically¹ it is α - α' (Iminobis ethylene)bis[6-fluoro-3,4,dihydro-2H-1-banzopyran-2methanol]. S-amloldipine(S-AMLO) is also an antihypertensive agent. Chemically² it is 2-[(2-Aminoethoxy) methyl] -4-(2chlorophenyl)-1,4-dihyhdro-6-methyl-3,5 pyridinedicarboxylic acid 3-ethyl 5-methyl ester. Fixed Combination of NEBI (5 mg) and S-AMLO(2.5mg) is available in the market as tablet. Literature survey revealed spectrometric³, HPLC⁴ and HPTLC⁵ methods for estimation of s-amloldipine alone or in combination with other drugs. Nebivolol is reported to be estimated by RP-HPLC⁶. But no analytical method has been reported so far for the simultaneous estimation of NEBI and S-AMLO from dosage formulation. A successful attempt has been made to estimate both these drugs simultaneously in tablet formulation by first derivative spectrophotometry.

RESULTS AND DISCUSSION

The results of estimation are shown in Table 1. The percent label claim was found in the range of 99.69-100.43%. To ascertain the accuracy and of the proposed methods recovery studies were carried out by standard addition method at three different levels. The percent recovery was calculated by following formula:

% recovery = (T-A/S x 100, where T is total amount of drug estimated, A is the amount of drug contributed by tablet powder(estimated by proposed method) and S is the amount of pure drug added.^{11,12} The results of recovery studies are shown in Table 1. The percent recovery was found in the range of 99.26-99.89 %. The standard deviation was below 2 % indicating the precision of the method.

The proposed method is found to be simple, accurate, precise and economical and can be employed for routine analysis of s-amloldipine and nebivolol in combined dose tablet formulation.

Table 1: Results of estimation in tablet and recovery studies

Formulation	Drug	Label claim (mg/tablet)	Amount found(mg/tablet)	%Label claim* ± SD	Mean % recovery** ± SD
NEBICARD-SM	NEBI	5	5.02	100.40± 0.10	99.81± 0.098
	S-AMLO	2.5	2.53	99.80± 0.10	99.56± 0.098

* mean of five observations, ** mean of three observations.

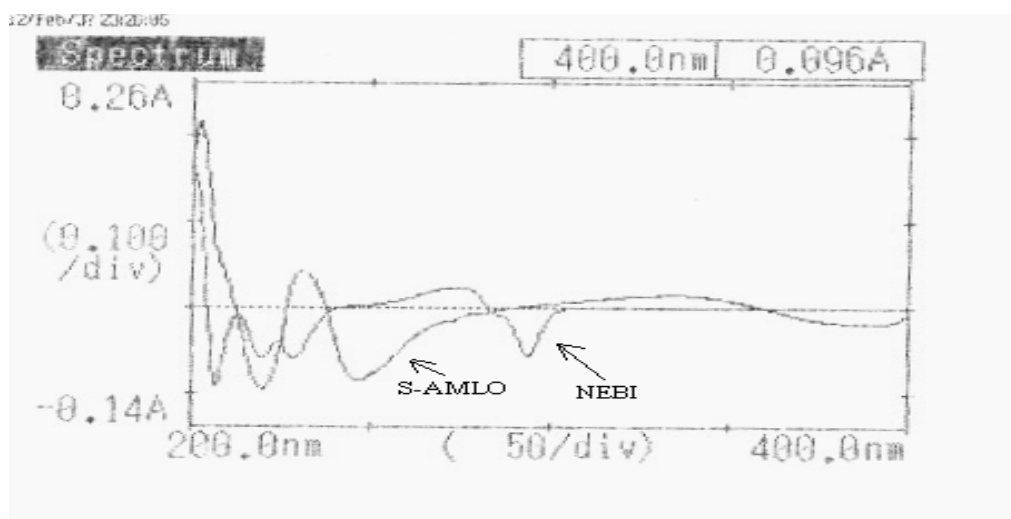


Fig.1: overlain spectra of NEBI and S-AMLO in first derivative mode
MATERIALS AND METHODS

A Shimadzu UV-Vis Spectrophotometer Model 1601 with spectral bandwidth of 3 nm and wavelength accuracy of 0.5 nm with automatic wavelength correction with a pair of 10 mm quartz cells was used in the experimentation. Methanol (A.R. grade) was used as a solvent.

Standard stock solutions of NEBI (100 µg/ml) and S-AMLO (100 µg/ml) were prepared in methanol^{8,10}. The stock solutions were individually diluted to get final concentration of 20 µg/ml each and the diluted solutions were scanned in 200-400 nm range. The first derivative spectra of both the drugs were obtained from derivative mode of the instrument (Fig.1). NEBI showed significant absorbance in the first derivative mode at 290.0 nm i.e., at zero crossover point of S-AMLO whereas S-AMLO was found to have significant absorbance in the first derivative mode at 242.0 nm i.e. at zero cross over point of NEBI. Hence the wavelength 290.0 was selected for analysis of NEBI and 242.0 nm was selected for analysis of S-AMLO.

To study Beer's Lambert law, the standard stock solutions of both the drugs were individually diluted to get different concentrations ranging from 10-60 µg/ml. Absorbances of diluted solutions in first derivative mode were measured at 290.0 nm for NEBI and 242.0 nm for S-AMLO. The graph plotted as absorbance vs. concentration indicated a linear relationship ($r^2 = 0.9990$ for NEBI and $r^2 = 0.9957$ for S-AMLO) over the concentration range under study.

For the estimation of both these drugs in tablet formulation, twenty tablets were weighed and the average weight was calculated. The tablets were then crushed to obtain fine powder. An accurately weighted quantity of tablet powder equivalent to about 5 mg NEBI and 2.5 S-AMLO was transferred to 25.0 ml volumetric flask, shaken with 10 ml methanol for 10 min. and the volume was made up to the mark with distilled water. The solution was mixed and filtered through Whatman grade 1 filter paper. The filtrate was appropriately diluted with methanol to get final concentration within the Beer's law range. Absorbance of diluted solutions was measured in the first derivative mode at 290.0 nm and 242.0 nm. The amount of NEBI and AMLO in diluted solutions was obtained from the standard calibration curve.

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