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DEVELOPMENT OF UV-VISIBLE SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF BALSALAZIDE CAPSULES

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ABSTRACT

Balsalazide is an anti-inflammatory drug used in the treatment of inflammatory bowel disease. It is usually administered as the disodium salt. New, simple and sensitive spectrophotometric methods for the determination of balsalazide have been developed for the quantitative estimation of from balsalazide capsule dosage form. The Method was developed and based on the condensation reaction of balsalazide with Ehrlich's reagent (p-dimethylaminobenzaldehyde) to from a yellow chromogen with λ_{max} at 402 nm. Beer's law is obeyed in the concentration range of 40-160 µg/ml. The proposed methods are statistically validated and found to be useful for the routine determination of balsalazide in capsules.

KEYWORDS: Balsalazide, Colorimetry, capsules, Validation.

INTRODUCTION

Balsalazide disodium[1-2] is chemically (E)-5-[[-4-[[(2-carboxyethyl) amino] carboxyl] pheny] azo]-2-hydroxy benzoic acid, disodium salt, dihydrate. It is a prodrug that is enzymatically cleaved in the colon to produce mesalamine (5-aminosalicylic acid), an anti-inflammatory drug. It is used in the treatment of mild to moderate ulcerative colitis.[3-5] Balsalazide disodium capsules contain granules of balsalazide disodium, which are insoluble in acid and designed to be delivered to the colon intact. Upon reaching the colon, bacterial azo reductases cleave the compound to release 5-aminosalicylic acid, the therapeutically active portion of the molecule, and 4-aminobenzoyl-β-alanine. Balsalazide disodium is not official in any pharmacopoeia. Literature survey revealed several spectrophotometric methods for its quantitative estimation in bulk drug and pharmaceutical dosage forms.[6-13] In the present work, two simple and sensitive colorimetric method were developed for the estimation of balsalazide in bulk drug and pharmaceutical dosage forms. In this method, balsalazide is treated with the carbonyl reagent p-dimethylaminobenzaldehyde (Ehrlich's reagent) to from a condensation product, which has absorption maximum at 402 nm. Spectrophotometric parameters are established for standardization of the method including statistical analysis of data.

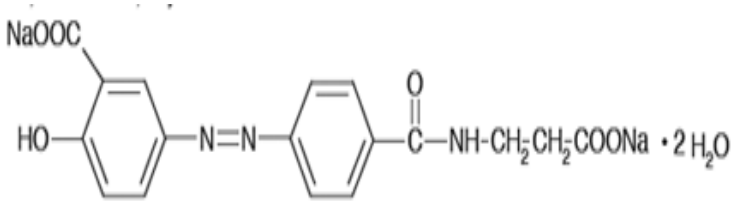

Figure 1: Structure of Balsalazide disodium.

EXPERIMENTAL

Instrument

All spectral and absorbance measurements were made on Shimadzu UV-VIS spectrophotometer – 2450.

Ehrlich's reagent (0.5% w/v)

All reagents used were of analytical grade.

Preparation of standard solution

A 1 mg/ mL stock solution of balsalazide was prepared by dissolving 100 mg of drug in 100 ml of double distilled water.

Sample preparation

Twenty capsules were weighed after which powdered was separated from each capsule. A quantity equivalent

to 750 mg of balsalazide disodium was weighed accurately, transferred to a beaker, dissolved in double distilled water, filtered through Whatmann filter paper No. 1 into 25 mL volumetric flask and made upto volume with distilled water to get a concentration of 1 mg/ml.

Assay procedure

Method

Aliquots of balsalazide ranging from 0.4 – 1.6 mL (1.0 mL = 1000 µg) were transferred into a series of 10 ml volumetric flasks. To each flask, 3 mL of Ehrlich's reagent (0.5% w/v) was added and shaken well and made up to volume with double distilled water. The absorbance of the yellow chromogen was measured at 402 nm against the reagent blank. The yellow chromogen was stable for more than 3 hours. The analytical curve was constructed by plotting concentration versus absorbance.

Sample analysis

Pharmaceutical formulation of balsalazide was successfully analysed by the proposed methods.

Appropriate aliquots were subjected to the above methods and the amount of balsalazide was determined from the calibration curves. The results of sample analysis are furnished in Table 2.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, molar absorptivity and Sandell's sensitivity are furnished in Table 1.

Table 1: Optical characteristics and precision of the proposed method.

Parameter	Method
λ_{max} (nm)	402 nm
Beer's law limits (µg/ml)	40-160
Molar absorptivity (L mol^{-1} cm^{-1})	2.382 x 10^3
Sandell's sensitivity	0.01384
(µg/cm^2/0.001 absorbance unit)	
Regression equation (*y)	
Slope (b)	0.00709
Intercept (a)	0.00515
Correlation co-efficient (r)	1.000
% RSD	0.4823
Standard error (SE)	0.0203

*y = a + bc where c is the concentration of Balsalazide in µg/ml

The regression characteristics like slope (b), intercept (a), correlation co-efficient (R), percent relative standard deviation (% RSD) and standard error (SE) were calculated and the results are summarized in Table 1.

The results of sample analysis showed that the drug determined by the proposed methods was in good agreement with the label claim proving the accuracy of the proposed methods.

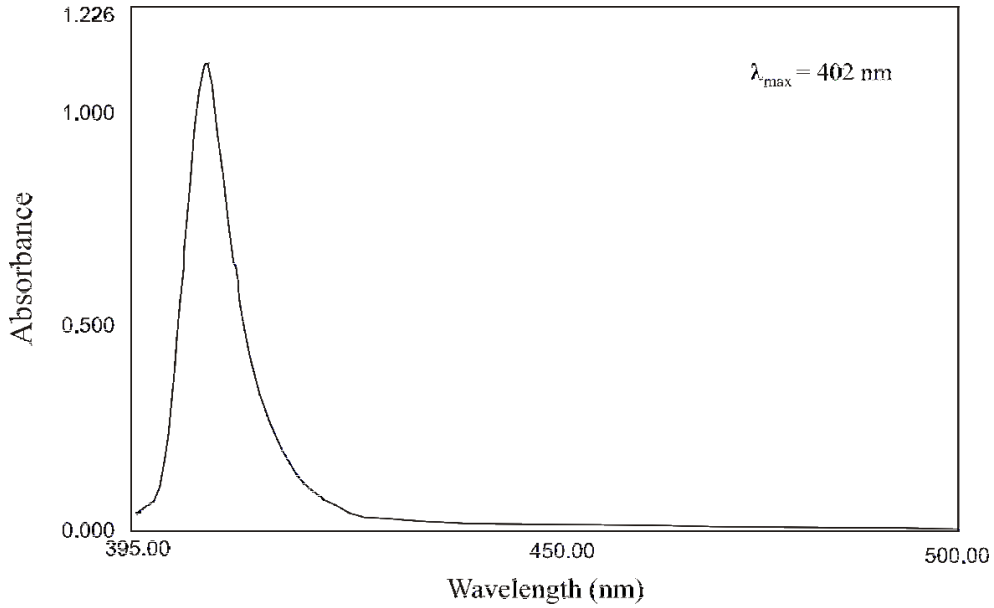

Fig. 2: λ_{max} of yellow chromogen.

Table 2: Assay and recovery of Balsalazide in dosage forms.

Drug	Labelled amount (mg)	Amount obtained (mg)*	Percentage recovery**
Cozabal	750	751	100.8%

*Average of six determinations
**Average of three determinations

To study the accuracy and reproducibility of the proposed methods, recovery experiments were carried out by adding a known amount of drug to preanalysed sample and the percentage recovery was calculated. The results are furnished in Table 2. The results indicate that there is no interference of other ingredients present in the formulations. Thus, the proposed methods are simple, sensitive, economical, accurate and reproducible and are useful for the routine determination of balsalazide disodium in bulk drug and its pharmaceutical dosage forms.

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