WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.074
Volume 8, Issue 3, 1185-1190. Research Article ISSN 2277– 7105

DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD FOR QUANTITATIVE ESTIMATION OF BALSALAZIDE FROM CAPSULE FORMULATION

Naveen Kumar G.S.*, Dinesh M., Gokul Nanda G. and Hanumanthachar Joshi

Sarada Vilas College of Pharmacy, Mysore-570004.

Article Received on
09 Jan. 2019,

Revised on 30 Jan. 2019,
Accepted on 19 Feb. 2019

DOI: 10.20959/wjpr20193-14386

***Corresponding Author**
Naveen Kumar G.S.
Sarada Vilas College of Pharmacy, Mysore-570004.

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 solubility of balsalazide in 0.1 N NaOH. The drug showed maximum absorbance at 454 nm and linearity (Lambert Beer's Range) was found in concentration range of 10-100 µg/ml and the standard curve equation was found to be y = 0.015x – 0.015 and R^2 value 0.998. The results of analysis were validated statistically and by recovery studies. The result of analysis was validated as per ICH guidelines and this method can be used for the routine analysis of balsalazide formulation.

KEYWORDS: Balsalazide, 0.1 N NaOH, UV method, Validation.

INTRODUCTION

Balsalazide disodium[1-2] is chemically (E)-5-[[-4-[[(2-carboxyethyl)amino]carboxyl]pheny]azo]-2-hydroxy benzoic acid, disodium 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 is

not official in any pharmacopoeia. Literature survey revealed several spectrophotometric methods for its quantitative estimation in bulk drug and pharmaceutical dosage forms.[6-12] But there is no method is reported, so in this work we attempt to develop a UV Spectrophotometric method for quantitative estimation of balsalazide formulation.

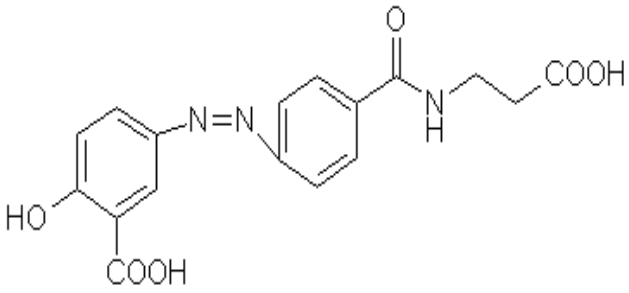

Figure 1: Structure of Balsalazide.

MATERIAL AND METHODS

Apparatus

Shimadzu UV-visible spectrophotometer (Model 2450) with 1 cm matched quartz cell was used in present study for spectral and absorbance measurements.

Reagents and Materials

All chemicals and reagents used were of analytical grade and double distilled water was used throughout the investigation.

- 0.1N NaOH: It was prepared according to I.P.1996
- Standard Stock Solution: Accurately weighed (100 mg) pure drug sample of balsalazide was transferred to100 ml (1000 µg/ml) calibrated volumetric flask, dissolved and made up to the mark with 0.1N NaOH solution.

Developed Method

(1) Scanning for determination of maximum absorbance for pure drug in 0.1 N NaOH solution and preparation of calibration curve. By using the stock solution of 1000 µg/ml, transferred 10 ml into 100 ml volumetric flask and made up the volume (200 µg/ml) and subsequently dilution was carried out by withdrawing different aliquots (0.5, 1.0, 2.0, 4.0, 5.0 ml) from standard solution were transferred into a series of 10 ml calibrated flasks and all were made up to the mark with 0.1 N NaOH solution and absorbance was measured at 454 nm against blank. A calibration curve was plotted from the absorbance values so obtained. A

representative spectra and calibration curve of balsalazide is reported in Figure 2 & 3 respectively.

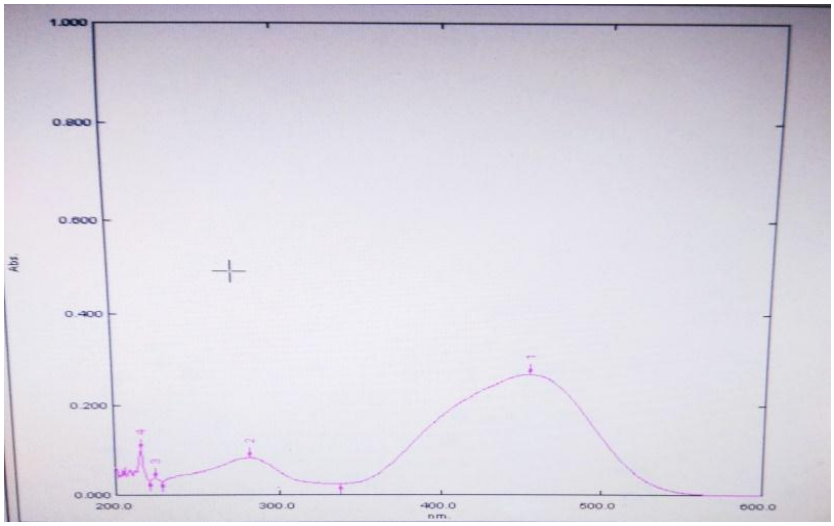

Figure 2: Spectra of Balsalazide (pure drug) in 0.1 N NaOH.

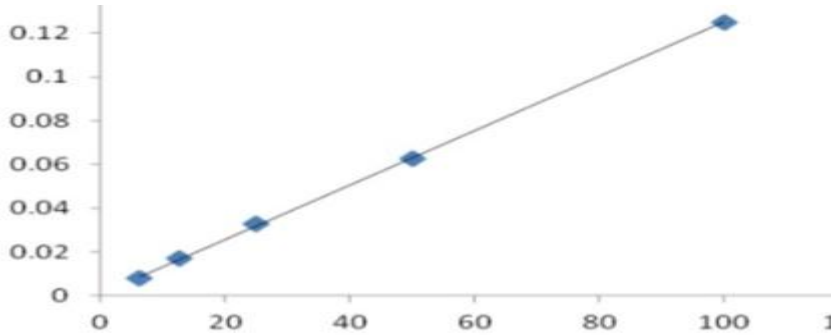

Figure 3: Calibration curve of Balsalazide.

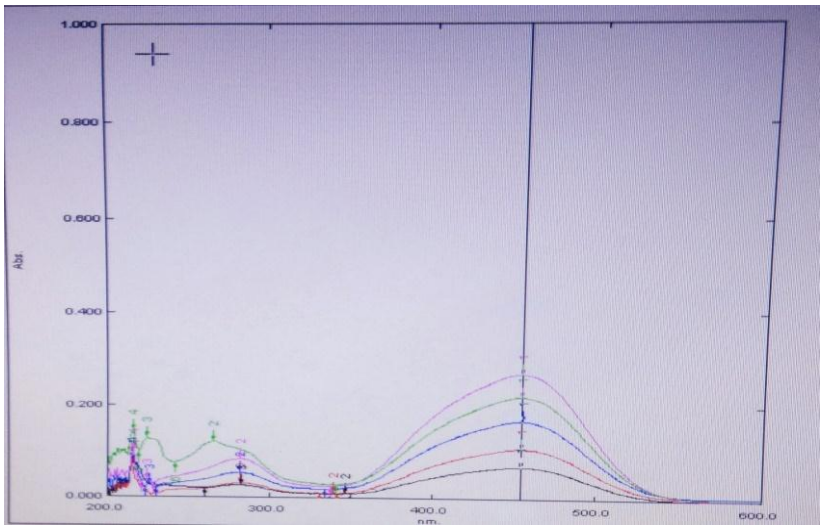

Figure 4: Overlay Spectra of Balsalazide (pure drug) in 0.1 N 0.1 N NaOH.

Analysis of capsule Formulation

Twenty capsules were weighed accurately the powder equivalent to 10 mg of balsalazide was weighed and dissolved in about 75 ml 0.1 N NaOH. The solution was shaken thoroughly for about 15-20 min, and filtered using Whatman No. 41 filter paper; residue was washed with 20 ml 0.1 N NaOH. Filtrate and washing were transferred to a 100 ml calibrated volumetric flask and 0.1 N NaOH was added up to the mark (200 µg/ml). The 4 ml of above filtrate was diluted to 100 ml with 0.1 N NaOH. Absorbance was measured at 454 nm wavelength maxima and the concentration of the drug in sample solution was determined from calibration curve. The results of analysis are presented in Table 2 respectively.

Accuracy (recovery test): Accuracy of the method was studied by recovery experiments. The recovery experiments were performed by adding known amounts of the drugs in powdered capsules. The recovery was performed at three levels, 60, 80 and 100% of balsalazide standard concentration. The recovery samples were prepared in aforementioned procedure. Three samples were prepared for each recovery level. The solutions were then analyzed and the percentage recoveries were calculated from the calibration curve.

Table 1: Quantitative parameters of spectrophotometric method.

Parameters	Value
λ_{max}/ nm	454
Beer's law limits, µg/ml	10-100
Regression equation	y = 0.015x - 0.015
Slope	0.015
Intercept	0.015
Correlation coefficient (r^2)	0.998

Table 2: Results of Analysis of Capsule Formulation and Recovery Studies.

Brand	Label claim	% Label claim Estimated*	Standard Deviation	% Recovery**
Cozabal	750µg/ml	99.45	0.240	98.98
Balacol	750µg/ml	99.17	0.180	99.12

*Average of six determinations

** Average of Recovery Studies at three different concentration levels

RESULTS AND DISCUSSION

UV method has been developed for the quantitative estimation of balsalazide from capsule formulation. The developed method is based on the solubility of balsalazide in 0.1N NaOH. The results of analysis from capsule formulation were within the permissible limits and the results of recovery studies reflect nil interference from excipients. The developed method was found to be simple, accurate and economical hence can be used for routine analysis of balsalazide from pharmaceuticals.

ACKNOWLEDGEMENT

The authors are thankful to The Management, Sarada Vilas College of pharmacy for their kind help and providing necessary facilities.

REFERENCES

1. Sweetman SC. Martindale: The Complete Drug Reference. 33rd ed. UK Pharmaceutical Press, 2002; 1212.
2. O'Neil MJ, editor. The Merck Index – An Encyclopedia of Chemicals Drug and Biological. 13th ed. NJ, USA. Merck & Co. Inc, 2001; 947-948.
3. Salil K, Bhattacharya, Parantapa Sen and Arunabha Ray: Pharmacology. 2nd ed, 2003; 334.
4. Prakash A and Spencer CM. Review of Pharmacology and Clinical Efficacy in Ulcerative Colitis Drugs, 1998; 56: 83.
5. Malathi S and Shivbalan S. Crohn's Disease. Gastro Enterology and Hepatology –I, 2006; 73(8): 723.
6. Naveen GS, Manohara YN and Channabasavraj KP. Development and Validation of Spectrophotometric methods for the Estimation of Balsalazide in Pharmaceutical Dosage Forms. International Journal of Chemical Sciences, 2008; 6(2): 497.
7. Naveen kumar GS, Manohara YN and Karunakar Hegde. Extractive Spectrophotometric Determination of Balsalazide in Pure Form and Pharmaceutical Formulations by Using Safranin-O and Methylene Blue. Asian Journal of Chemistry, 2009; 21(2): 1624-26.
8. Anandakumar K, Varadharajan K, Ayyappan T, Nageswara Rao P and Sujatha K. Estimation of Balsalazide in Bulk and in Formulation by UV-Visible Spectrophotometry. Research Journal Pharmacy and Technology, 2008; 1(4): 472-74.
9. Maheswari P, Appala raju S and Shobha Manjunath. Development and Validation of Spectrophotometric Methods for the Estimation of Balsalazide in Bulk and

Pharmaceutical Formulations. International Journal of Chemical Sciences, 2009; 7(2): 1467-71.

10. Naveen Kumar GS, HarishKH, Dinesh.M and Hanumathachar Joshi. Development and validation of UV-Spectrophotometric estimation of Balsalazide in bulk and capsules. Universal Journal of Pharmacy, 2013; 2(1): 143-47.
11. Naveen Kumar GS, Harish KH, Hanumanthachar Joshi.Validated spectrophotometric method for the determination of Balsalazide using phenol red and bromo cresol green. Universal Journal of Pharmacy, 2016; 5(6): 20-24.
12. Eswara Rao Bammidi, Vaikuntarao Lakinani, and Pavitra Paila. Development and validation of stability indicating HPLC method for Balsalazide in bulk drug development. International Journal of Modern Chemistry and Applied Science, 2016; 3(1): 315-22.