WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 5.990
Volume 4, Issue 6, 1094-1099. Research Article ISSN 2277– 7105

SPECTROPHOTOMETRIC ESTIMATION OF ZALTOPROFEN FROM BULK DRUG AND TABLET DOSAGE FORM

Rajan V. Kalamkar[1*], Shailesh J. Wadher[1], Sunita S. Gagare[2] and Ashish S. Jain[2]

[1]School of Pharmacy, S.R.T.M. University, Nanded.

[2]Shri D.D. Vispute College of Pharmacy & Research Center, Panvel.

Article Received on
29 March 2015,

Revised on 22 April 2015,
Accepted on 13 May 2015

***Correspondence for Author**
Rajan V. Kalamkar
School of Pharmacy,
S.R.T.M. University,
Nanded.

ABSTRACT

Two Simple, accurate, precise and sensitive spectrophotometric methods for estimation of Zaltoprofen (ZAL) have been developed and validated. The zero order spectroscopic method (Method I) and area under curve method (Method II) have developed. The proposed methods are validated according to ICH Q2B guidelines. The Zaltoprofen gives maximum absorbance at 227nm in Methanol: Water (1:4) and observed linearity 2-18 µg/ml for zero order method and area under curve method. The stability of drug in Methanol: Water (1:4) has been studied and drug shows good stability. The recovery by method I and method II are 99.87 ± 0.532, 99.62±0.712 respectively. The both spectrophotometric methods can be applied for routine analysis of Zaltoprofen in tablet formulation and in bulk drug.

KEYWORDS: Zero order method, area under curve method, UV spectrophotometer, absorbance.

INTRODUCTION

Zaltoprofen is available in tablet dosage form. Zaltoprofen (ZAL) (±)-2-(10,11-dihydro- 10-oxodibenzo [*b,f*] thiepin-2-yl) propionic acid and its structure is shown in Fig.1. Zaltoprofen (ZLT) is a non-steroidal anti-inflammatory drug, and has excellent effects even on post-surgery or post-trauma chronic inflammation. It is used in the treatment of rheumatoid arthritis, osteoarthritis, and other chronic inflammatory Pain conditions.

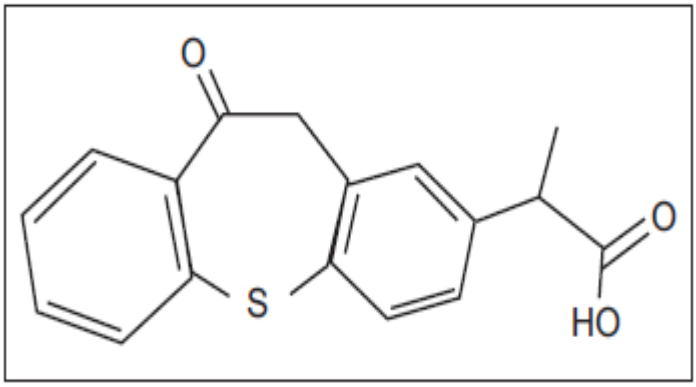

Fig. 1 Structure of Zaltoprofen

Literature survey reveals few analytical methods for determination of Zaltoprofen using UV Spectroscopy and HPLC in pharmaceutical formulation have been reported. However, there are no simple and economic reported methods for estimation of Zaltoprofen. The current research work deals with development of UV spectrophotometric methods and its validation as per ICH guidelines. The devised methods were found to be simple, reliable, faster and more economic than other reported methods.

MATERIALS AND METHODS

Instruments & Chemicals

Pharmaceutically pure samples of ZAL were obtained as gifts from IPCA Lab ltd. Mumbai & Methanol AR grade (Research Lab) and distilled water (1:4) was used as solvent in the study. Double beam UV spectrophotometer Lab India 3000 with a pair of 10mm matched quartz cells was used to measure absorbance of the resulting solution.

Preparation of standard stock solution

Accurately 10 mg of ZAL was weighed separately and transferred to 100ml volumetric flask. Drug was dissolved by 10 min sonication in 20 ml methanol and then volume was made up to the mark with distilled water. The standard stock solutions (100µg/ml) were further diluted separately to obtain working standard of concentration 10µg/ml of ZAL.

Study of spectra and selection of wavelengths

Each working standard solution was scanned between the range 200-400 nm in 1 cm cell against blank. Maximum absorbing wavelength of ZAL was selected from spectral. The λ max for ZAL was 227nm.

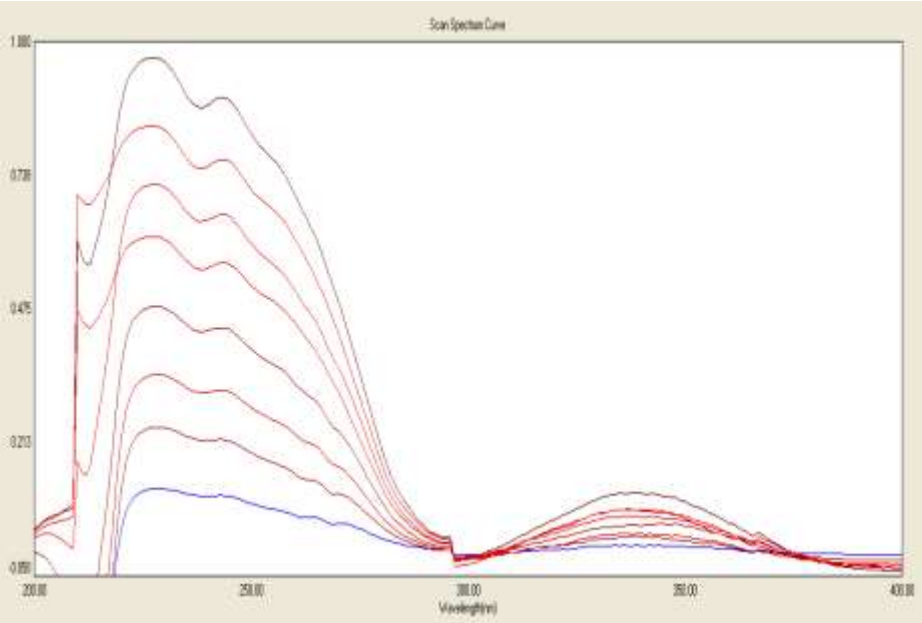

Fig.2 Overlain spectra of Zaltoprofen of different concentrations.

Zero Order Method (Method I)

i) Calibration Curve: The absorbances were recorded for 2-18 µg/ml at 227 nm (λmax of ZAL). From this calibration curve was plotted.

Area under Curve Method (Method II)

ii) Calibration curve: The area was recorded for 2-18 µg/ml at 222 – 232 nm. From this, calibration curve were plotted.

Procedure for analysis of tablet formulation

Twenty tablets were accurately weighed and average weight was calculated. The tablets were triturated to a fine powder. An accurately weighed quantity of powder equivalent to 10 mg ZAL was dissolved in 50 ml methanol and sonicated for 10 min and volume was made up to 250ml by distilled water. The solution was filtered through Whatman filter paper No 41 and aliquot portion of filtrate was diluted to produce solution having concentration of 4µ/ml of ZAL. The absorbance and area of sample solution was measured at selected wavelengths and the concentration of the drugs was estimated using zero order method and area under curve method. The analysis procedure was repeated six times and the results are depicted in Table 3.

Table 1: Linear Regression Analysis of Calibration Curves with Their Respective Absorptivity Values

Parameters	Method I	Method II
Beer's law limit (µg/mL)	2-18	2-18
Correlation coefficient (r)	0.9997	0.9998
Molar absorptivity (lit/mole/cm)	13796.17	191999.43
Slope	0.045	0.664
Intercept	0.021	0.131
LOD (µg/mL)	0.5	1.2
LOQ (µg/mL)	1.0	1.5

Table 2 Results of recovery studies

Level of Recovery %	Amount of pure drug added (mg)	Method I % recovery	Method II % recovery
80	4	100.61	98.52
100	5	98.82	100.47
120	6	100.23	99.87
Mean % Recovery		99.87	99.62
SD*		0.532	0.712
CV**		0.398	0.113

* Mean of six readings

Table 3 Results of analysis of tablet formulation

Label Claim (mg)	Method I % ± SD (n=6)*	Method II % ± SD (n=6)*
80	100.12 ± 0.216	99.46 ± 0.114

* Mean of six readings

Table 4 Results of intermediate precisions:

Day	Method I	Method II
	% Label claim estimated (Mean ±%RSD)*	% Label claim estimated (Mean ±%RSD)*
Intraday	99.28 ± 0.874	99.98 ± 0.931
Interday	99.54 ± 0.563	98.84 ± 0.328

* Mean of six readings

RESULTS AND DISCUSSION

The Zero order method is simple, rapid and requires only the accurate values of absorbance of the drug solution at maximum absorbing wavelength. The method requires recording of absorbance and few calculations that can be used with any model of spectrophotometer. The maximum absorbance observed at 227nm in Methanol: Water (1:4). In Area under curve method, the absorptivity values of the drug were determined at 222 – 232 nm wavelength

range. Total area under curve of a mixture at wavelength range is equal to the sum of area under the individual component at that wavelength range. In these two methods Methanol : Water (1:4) is used, therefore methods are more economical as compare to available methods. Standard calibration curves for ZAL was linear with correlation coefficients (r) values in the range of 0.9997 – 0.9998 at all the selected wavelengths and the values were average of three readings with standard deviation in the range of 0.2465 – 0.7126.The methods were repeated three times in a day and the average % RSD was found to be 0.874 for method I and 0.931 for method II. Similarly the method was repeated for three different days and average % RSD was found to be 0.563 for method I and 0.328 for method II. The accuracy of the methods was confirmed by recovery studies from tablet at three different levels of standard additions; recovery in the range of 99.62 – 99.87% justifies the accuracy of method.

CONCLUSION

The proposed UV spectrophotometric methods are a simple, accurate, precise, rapid and economical for the estimation of ZAL in bulk drug and tablet dosage form. The proposed methods use inexpensive reagents, solvents and instruments that are available in laboratories. Hence, these methods can be conveniently adopted for the routine analysis in quality control laboratories.

ACKNOWLEDGEMENT

We would like to thank IPCA Labs Ltd, Mumbai, for providing pure drug samples for this study and Principal, Shri D.D. Vispute College of Pharmacy & Research Center, Panvel, for providing us the research facility & Mr. Swapnil Pujari for help in timely providing the chemicals. We are also thankful to Dr. Kaustubh Jinturkar for assistance in the study.

REFERENCES

1. Aher KB, Bhavar GB and Joshi HP. *Journal of Current Pharmaceutical Research*, 2012; 9(1): 49-54.
2. Thangabalan B and Kuma PV. *Int. J. Drug Dev. & Res*, 2012; 4(4): 275-278.
3. Gowramma B and Meyyanathan SN. *Int J Pharm Bio Sci*, 2013; 4(1): 883 – 889
4. Gowramma B, Meyyanathan SN, Gomathy S, Babu B, Krishnaveni N and Suresh B. *Int J Pharm Pharm Sc*., 6(2); 584-587.
5. Tank SK, Sen DB, Sen AK and Seth AK. *Pharma Science Monitor*, 2013; 4(4-1).
6. Beckett AH and Stanlake JB. Practical Pharmaceutical Chemistry. CBS publishers and distributors New Delhi, Forth edition part two., 2005; 284-288.

7. ICH Harmonized Tripartite guideline. Validation of Analytical Procedures text and Methodology Q2 (R1) Currant step 4 version, Parent guideline dated 27 November 1994 (Complementary guideline on Methodology dated 6 November 1996 incorporated in November 2005.
8. S.R. Bhagade. *IJPSR*, 2013; 4(11): 4432-4434.
9. Mishra AK, Kumar M, Mishra A, Verma A and Chattopadhyay P. *Archives of Applied Science Research*, 2010: 2(3); 207-211.
10. Kutty SV, Eapen SC, Shameer M, Faizal PP. *IJPSDR*, 2012: 4(1); 74-76.
11. Saikiran BH, Johnny SK and Madhuri PL. *IJPCBS*, 2013: 3(3); 729-731.
12. Malhotra D, Kalia A and Tomar S. *Int J Pharm Pharm Sci*., 2011: 3(4); 299-302.