Academic Sciences Asian Journal of Pharmaceutical and Clinical Research

Vol. 4, Suppl 1, 2011 ISSN - 0974-2441

Research Article

SIMPLE AND RAPID SPECTROPHOTOMETRIC ESTIMATION OF NIMESULIDE IN BULK DRUG AND LIQUID DOSAGE FORMULATIONS

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ABSTRACT

A simple, highly sensitive and accurate method has been developed for the estimation of Nimesulide in liquid dosage form. The proposed method is based on the principle that Nimesulide can exhibit absorption spectra of wavelength maxima at 295 nm in methanol. This method can be successfully used for the analysis of drug in marketed liquid dosage formulations in the range of 10-50µg/ml. The correlation coefficient, percentage of relative standard deviation and percentage recovery was found to be 0.9964, 0.93% and 101.25-106.00% respectively. There was no interference of the excipients. This method have been validated for linearity, accuracy and precision and found to be rapid, precise and economical.

Keywords: UV spectrophotometry, Nimesulide, Liquid dosage form, Chloroform extraction.

INTRODUCTION

Nimesulide (NIME) is chemically N-(4-nitro-2-phenoxyphenyl) methane sulfonamide, a well known acidic non-steroidal anti-inflammatory, analgesic and antipyretic drug [1-3]. It is a significant and selective COX-2 inhibitor[4,5]. This drug is not official in any pharmacopoeia. The literature survey revealed that analytical methods reported for the estimation of NIME include HPLC[6-8], spectrophotometry[9-13], fluorimetry[14], voltametry[15], capillary electrophoresis[16], HPTLC[17] and ion association titration[18] in pharmaceutical formulations. However, there is no publication concerning the analysis of NIME in bulk and liquid dosage formulations by simple UV method. The aim of the present work is to describe a simple, rapid and sensitive UV method for estimation of NIME in liquid dosage formulations.

MATERIALS AND METHODS

The present work was carried out on a SYSTRONICS-double beam UV-VIS spectrophotometer 2203 with 2 nm slit width and a pair of 1 cm matched quartz cells.

Working standard solution

Pure Nimesulide drug was purchased from Sigma-Aldrich Company and used without any identification or purification test. Standard stock solution of Nimesulide, was prepared (100 µg/ml) in a 100 ml, calibrated, volumetric flask using methanol as the solvent. Different volume of the primary standard was taken and diluted to get a concentration in the range of 5-50 µg/ml. These were freshly prepared and scanned in the UV region. The absorption maxima observed at 295 nm was recorded. The calibration curve was prepared by plotting absorbance versus concentration, which followed the Beer and Lambert's law and gave a straight line (r = 0.9964).

Estimation of Nimesulide from liquid dosage form

Fifteen bottles of Nimesulide syrup were poured in a calibrated 1000 ml volumetric flask and shaked well. Immediately syrup in ml, equivalent to 100 mg of Nimesulide was transferred to a 100 ml volumetric flask using a calibrated pipette and sufficient deionised double distilled water was added. Shaked well, filtered and extracted thrice in 20, 15 and 10 ml of chloroform. All the extracts were collected in a beaker and evaporated to dryness. The product was sufficiently air dried and weighed. The collected amount was equal to 100.30 mg of Nimesulide. It was confirmed by TLC and melting point. Then a stock solution was prepared of 100 µg/ml in methanol, This was further diluted to make the working solutions. Absorbance versus concentration was plotted which gave a straight line. The amount of Nimesulide was calculated from calibration curve and the results are shown in Table 1.

Interference or absence of interference of excipients was confirmed by performing recovery studies, for which standard addition method was employed. Known amounts of pure drug (50, 80 and 100%) were added in triplicate. From recovery studies it was confirmed that there was no interference of excipients and results are shown in Table 2.

RESULTS AND DISCUSSION

Nimesulide showed wavelength maxima at 295 nm in methanol. The calibration curve was found to be linear in the range of 10-50 µg/ml. The correlation coefficient, percentage of relative standard deviation and the percentage recovery was found to be 0.9964, 0.93% and 101.25-106.00 % respectively.

The LOD and LOQ were calculated according to ICH guideline as LOD = 3.3σ/S and LOQ = 10σ/S, where σ is the standard deviation of the lowest standard concentration and S is the slope of the standard curve. LOD is the lowest concentration of an analyte that an analytical process can reliably detect and LOQ is the lowest concentration of the standard that can be measured.

From the results it was concluded that the excipients present in the formulation do not interfere in the estimation of Nimesulide. This proposed method can be successfully used for its analysis and quality control of marketed liquid dosage preparations with good precision, sensitivity and accuracy.

Table 1: Optical and Statistical Data

Parameters	Values
Maximum wavelength λmax	295 nm
Calibration curve range	10-50µg/ ml
Molar extinction coefficient	1.53×10^{4} l mol^{-1} cm^{-1}
Sandell's sensitivity	1×10^{-4} µg/cm^{2}
Regression equation	Y=0.096781 X+0.159998
Slope	0.096781
Intercept	0.159998
Percentage relative standard deviation (%RSD)	0.93
Correlation co-efficient (r)	0.9964
Limit of detection (LOD)	0.025µg/ml
Limit of quantitation (LOQ)	0.77µg/ml

Table 2: Accuracy of the proposed method (standard addition method)

Conc. of drug in Formulation (µg/ml)	Conc. of pure drug added (µg/ml)	Total conc. of drug found (µg/ml)	%Labeled Claim Mean±sd
5	5	10.3	106.00±0.05
5	8	13.1	101.25±0.04
5	10	15.3	103.00±0.02

*Average of three determinations; Sd: Standard deviation

ACKNOWLEDGEMENT

We are wishing to thank Er. M. K. Dash, the Chairman of Dadhichi College of Pharmacy, Vidya Vihar, Sundargram, Cuttack, Orissa for providing necessary facilities to carry out this research work.

REFERENCES

1. Biscarini L, Patoia L, Del Favero A. Nimesulide. A new non-steroidal anti-inflammatory agent, Drugs Today 1988, 24:23-27.
2. Piel G, Pirotte B, Delneuville I, Neven P, Llabres G, Delarge J, Delattre L. Study of the influence of both cyclodextrin and l-lysine on the aqueous solubility of nimesulide; isolation and characterization of nimesulide-l-lysine-cyclodextrin complexes, J Pharm Sci 1997, 86:475-79.
3. Singh A, Singh P, Kapoor VK. Analytical profiles of drug substances and excipients. Academic Press, New Jersey, 2001, 28:201.
4. Bakhle YS. Nimesulide and cox-2 inhibitors, Lancet 1999, 354:772.
5. Dhir A, Naidu PS, Kulkarni SK. Neuroprotective effect of nimesulide, a preferential cox-2 inhibitor, against pentylenetetrazol (PTZ)-induced chemical kindling and associated biochemical parameters in mice, Seizure 2007, 16: 691-97.
6. Nagaralli BS, Seetharamappa J, Gowda BG, Melwanki MB. High-performance liquid chromatographic method for the determination of nimesulide in pharmaceutical preparations, J Anal Chem 2003, 58: 873-75.
7. Nimje H, Wate SP, Dharkar DP, Razdan R. Simultaneous RP-HPLC determination of nimesulide and tizanidine in tablets, Indian J Pharm Sci 2007, 69:281-83.
8. Jaworowicz DJ, Filipowski MT, Boje KMK. Improved high-performance liquid chromatographic assay for nimesulide, J Chromatogr B 1999, 723: 293-99.
9. Kamalapurkar OS, Harikrishna Y. UV spectrophotometric estimation of nimesulide, Eastern Pharmacist 1997, 40:145-46.
10. Altinoz S, Dursun OO. Determination of nimesulide in pharmaceutical dosage forms by second order derivative UV spectrophotometry, J Pharm Biomed Anal 2000, 22: 175-82.
11. Chandran S, Saggar S, Priya KP, Saha RN. New ultraviolet spectrophotometric method for the estimation of nimesulide, Drug Development and Industrial Pharmacy 2000, 26: 229-34.
12. Chen X. Determination of nimesulide in suppositories by UV spectrometry, Zhongguo Xiandai Yingyong Yaoxue 2007, 24: 151-53.
13. Florea M, Monciu CM, Andritoiu ML, Bacanu LG. Spectrophotometric determination of nimesulide through ion-pair complex formation with hexadecyltrimethylammonium bromide, Farmacia 2008, 6: 639-46.
14. Lakshmi CSR, Reddy MN, Naidu PY. Fluorimetric determinatio-n of nimesulide with N-(1-naphthyl)ethylenediamine, Indian Drugs 1998, 35: 519.
15. Alvarez-Lueje A, Vasquez P, Nunez-Vergara LJ, Squella
16. JA.Voltammetric study of nimesulide and its differential pulse polarographic determination inpharmaceuticals, Electroanalysis , 9:1209-13.
17. Macia A, Borrull F, Calull M, Aguilar C. Capillary electrophoresis for the analysis of non-steroidal anti-inflammatory drugs, Trends in Analytical Chemistry 2007, 26: 133-53.
18. Patravale V, D'Souza S, Narkar Y. HPTLC determination of nimesulide from pharmaceutical dosage forms, J Pharm Biomed Anal 2001, 25: 685-88.
19. Constantinescu IC Florea M, Arama CC, Nedelcu A, Monciu CM. Assay of nimesulide by ion association titration, Farmacia 2009, 57:267-71.