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Quantitative estimation of Diclofenac sodium in marketed formulation by using mixed solvency approach

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Abstract

The proposed method is new, simple, environmentally friendly, accurate, reproducible, precise and validated statistically for simultaneous estimation of diclofenac sodium in bulk drug and tablet dosage form. The optimized methods showed good reproducibility and recovery with standard deviation of < 1.0% and percent relative standard deviation less then 2.0%, standard error in case of recovery studies are satisfactorily low and allow estimation of diclofenac sodium in concentration ranges employed for this purpose in the assay of bulk drug and tablets.

Key-Words: Diclofenac Sodium, Spectrophotometric method, Hydrotropic agent

Introduction

The term hydrotropy (mixed solvency) has been used to designate the increase in solubility of various substances in water due to the presence of large amounts of additives[1,2]. Diclofenac Sodium(DS) is chemically Sodium salt of 2-[{2,6-dichlorophenyl}amino] benzene acetic acid. It is having anti-inflammatory and analgesic properties[2,3]. Literature survey revealed that chromatographic method[4] was reported for its estimation from tablet dosage form and spectroscopic methods for estimation in combine dosage forms[5]. Hence an attempt has been made to develop simple, sensitive, economical, rapid, precise and accurate methods to analyze the drugs smoothly. There was marked enhancement in the solubility of DS in 0.6 M urea and 0.4 M sodium acetate solution (hydrotropic agent) as compared to the solubility in distilled water and buffer solutions. Therefore, it was thought worthwhile to extract out the drug from fine powder of tablets with 0.6 M urea and 0.4 M sodium acetate solution to carryout the spectrophotometric analysis.

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Material and Methods

Instrumentation

UV-Visible double beam spectrophotometer, Shimadzu model-1700 having spectral bandwidth 3nm and of wavelength accuracy ±1nm, with 1cm quartz cells was used. All weighing were done on electronic balance (Shimadzu, Model AY - 120).

Reagents and Chemicals

DS was obtained as gift sample from Zenith Pharma Ltd., Indore (MP). The tablet dosage form, Diclonac (50 mg) was procured from the local market,Indore,India. 0.6 M urea and 0.4 M sodium acetate was selected as hydrotropic solubilizing agent. All other material used was of analytical reagent grade. All other material used was of analytical reagent grade.

Preliminary solubility studies of drugs[6]

Solubility of both drugs was determined at 28 ± 2 ^{0}C. An excess amount of drug was added to two screw capped 30ml glass vials containing different aqueous systems viz distilled water, buffer of pH 6.4, buffer of pH 8.2, 0.1 M sodium acetate and 1.0 M urea. The vials were shaken mechanically for 12 h at 28+1˚ in a mechanical shaker. These solutions were allowed to equilibrate for next 24 h and then centrifuged for 5 min at 2000 rpm. The supernatant liquid was taken for appropriate dilution after filtered through whatmann filter paper # 41 and analyzed spectrophotometrically against corresponding solvent blank. After analysis, it was found that the enhancement in the solubility of DS was found satisfactory in 0.6 M urea and 0.4 M sodium acetate solution as compared to solubility studies in other solvents.

Preparation of standard stock solution of DS

About 50 mg of DS was accurately weighted and transferred to 50ml of volumetric flask separately. 20 ml, mixed solvent was used to solubilize after shaking for 10 to 15 minutes. Rest of the volume was made up with distilled water to get solution of 1000µg/ml. Stock solutions of 100µg/ml of drug was prepared by further dilution. The spectra exhibit major absorbance maxima at 277 nm for DS. Beers-Lambert law obeyed in the range of 5-35 µg/ml for DS.

Analysis of Tablet Formulation[7,8]

Twenty tablets were taken and their average weight was determined, they were crushed to fine powder. Then powder equivalent to 50 mg (50.41 mg) of DS was taken in 50ml volumetric flask and 20 ml, 0.6 M urea and 0.4 M sodium acetate solution was used to solubilize after shaking for 10 to 15 minutes. Rest of the volume was made up with distilled water to get solution of 1000µg/ml. Stock solutions of 100µg/ml of drug was prepared by further dilution. The supernatant liquid was transferred to 50ml of volumetric flask through a whatman No-41 filter paper. The residue was washed twice with water and the combined filtrate was made up to 50ml mark with water. The above solution was further diluted to get a solution containing 10 µg/ml of DS. The results of analysis were given in Table 1.

Recovery studies

To check the accuracy of the developed methods and to study the interference of formulation additives, analytical recovery experiments was carried out by standard addition method. From that total amount of drug found and percentage recovery was calculated. The results were reported in Table 2.

Validation of the developed methods[9]

The developed methods for estimation of DS was validated as per ICH guidelines.

Accuracy

To check the accuracy of the developed methods and to study the interference of formulation additives, analytical recovery experiments was carried out by standard addition method. Total amount of drug found and percentage recovery was calculated and results were reported in Table 2.

Precision

Precision of the method was verified by repeatability and intermediate precision studies.

Repeatability

To check the degree of repeatability of the methods, suitable statistical evaluation was carried out. Five samples of the tablet formulations were analyzed for the repeatability study. The standard deviation, coefficient of variance and standard error was calculated. The results were reported in Table 1.

Results and Discussion

All UV spectrophotometric methods were found to be simple, accurate, economic and rapid for estimation of DS in tablet dosage form. By performing these methods it was found that drug shown good regression value at their respective wavelengths and the recoveries were within 99.03 -101.81% for DS. The optimized methods showed good reproducibility and recovery with standard deviation of < 1.0% and percent relative standard deviation less then 2.0%.

Hence, the proposed methods could be successfully applied to the determination of DS in the commercially available bulk and tablet dosage form. Thus, it may be concluded that the proposed methods of analysis are new, simple, cost-effective, environmentally friendly, safe, accurate and reproducible. There was no interference of urea and sodium acetate solution in the estimation. The proposed method can be successfully employed in the routine analysis of DS containing dosage forms.

Conclusion

It is thus concluded that the proposed method is new, simple, cost effective, accurate, safe, free from pollution and precise and can be successfully employed in the routine analysis of Poorly water soluble drugs in pharmaceutical dosage forms.

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Table 1: Result of Pharmaceutical Formulation Analysis

Parameters	DS
Label claim (mg/Tab)	50
Found (mg/Tab)	49.03
Drug content[a]	100.77
±S.D	0.434
%COV	0.911
SE	0.183

[a]Value for drug content (%) are the mean of six estimation, S.D: Standard deviation , COV: Coefficient of variance and S.E: Standard error

Table 2: Result of Recovery studies

Drug	Label claim(mg/tab)	Amount (mg/ml)		% Recovery±S.D	COV%
		Taken	Added		
DS	50	30	5	101.22±0.093	0.421
		60	10	100.33±0.520	0.551
		90	15	100.93±0.171	0.152

%Recovery is mean of three estimation, S.D is standard deviation and COV is coefficient of variance

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