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Research Article

Unique UV Spectrophotometric Method For Reckoning of Aceclofenac in Bulk and Pharmaceutical Dosage Forms Using Hydrotropic Agents

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Abstract: Aceclofenac, chemically, a phenylaceticacid derivative, has antiinflammatory and analgesic properties. It is a potent inhibitor of cyclo-oxygenase which is involved in the production of prostaglandins. In present work, a selective, specific, sensitive and economical hydrotropic agent assisted spectroscopic method using 1M sodium bicarbonate and 1M urea (50:50% v/v), as hydrotropic agent; to increase the solubility of poorly water-soluble Acelofenac, has been developed for the estimation of Aceclofenac in Bulk and its pharmaceutical dosage forms. An absorption maximum was found to be at at273.6nm where sodium bicarbonate, urea and other excipients did not show any absorbance above216nm and thus no interference in the estimation. Aceclofenac was obeyed Beer's law in the concentration range from 10-60 µg / ml. Proposed method was validated according to ICHguidlines and values of accuracy, precision and other statistical analysis were found to be in good accordance with the prescribed values with correlation coefficient of 0.9997. The percentage recovery of Aceclofenac ranged from 99.8 to 100.2 % in pharmaceutical dosage form. Results of the analysis for accuracy, precision, LOD, LOQ and were found to be satisfactory. The proposed method is simple, rapid and suitable for the routine quality control analysis.
Keywords: Aceclofenac, Hydrotropy, UV Spectrophotometry

INTRODUCTION

Aceclofenac, chemically, 2-[2-[2-[(2, 6-dichloro phenyl) amino] phenyl [acetyl] oxyacetic acid [1, 2]. Aceclofenac, a phenyl acetic acid derivative, has anti inflammatory and analgesic properties. It is a potent inhibitor of cyclo-oxygenase which is involved in the production of prostaglandins [3]. The chemical structure of Aceclofenac is shown fig.1.

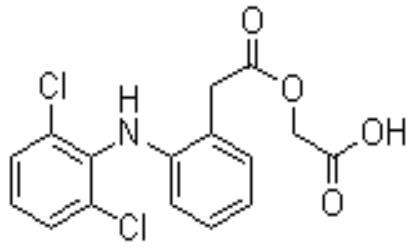

Fig 1: Chemical structure of Aceclofenac

Aceclofenac is practically insoluble in water so hydrotropic agents utilized to increase the water solubility [4]. Urea and sodium bicarbonate are the most common examples of hydrotropic agents. The solubility of various poorly water-soluble drugs was increased by hydrotropic solubilization phenomenon. Literature survey revealed that HPLC [5], densitometric [6], spectrofluorimetric [7] and colorimetric [8] methods have been reported for the estimation of aceclofenac in pharmaceutical dosage forms. To the best of our knowledge, there is no work in the literature reported about the Spectrophotometric method for the analysis of Aceclofenac using hydrotropic agent Therefore, it was thought worth wile to employ these hydrotropic solutions to extract out the drug from fine powder of tablets to carry out Spectrophotometric estimation [9-10].

MATERIALS AND METHODS

Instrumentation

Spectrophotometer used was Double beam UV-Visible spectrophotometer with 10mm matched quartz cell Model- UV-1700 PHARMASPEC**.** Make – shimadzu, Japan and Analytical balance: shimadzu, Japan AX 200.

Chemicals and reagents

All the reagents and chemicals used were AR grade. Aceclofenac were purchased from, , , Ltd. Respectively.

METHOD DEVELOPMENT

Preparation of standard stock solution and calibration curve:

Standard stock solution of Aceclofenac 100 µg /ml was prepared in mixed hydrotropic solution comprises sodium bicarbonate and urea .From this stock solution, appropriate dilution was made and scanned in the uv range 200-400 nm.The absorbance of Aceclofenac was found to be 273.6nm. The solubility of Aceclofenac was increased more than 16 times in mixed hydrotropic solution as compared with distilled water. This increased solubility of Aceclofenac is due to the hydrotropic solubilization phenomenon. Aliquots of in the range of 10-60 µg /ml were prepared with the same solvent and scanned under Photometric mode for Absorbance at 273.6 nm (Fig-1). A calibration curve was plotted taking an absorbance on Y-axis against concentration of standard solution on X-axis (Fig-2). The method was applied for Test sample solution and was found to be satisfactory for the analysis of dosage forms given in Table-2.

METHOD VALIDATION

The method was validated for different parameters like Linearity, Accuracy and Precision. The method was substantiated for different parameters like Linearity, Accuracy and Precision.

Linearity

Fresh aliquots were prepared from the stock solution (100 µg/ml) ranging from 10-60 µg/ml. The samples were scanned in UV-Visible spectrophotometer using 1M sodium bicarbonate and 1M urea in water is considered as blank. It was found that Aceclofenac exhibit linearity between the 10-60 µg/ml (Table -3).

Accuracy

Accuracy of the method confirmed by studying recovery at 3 different concentrations for 80, 100, and 120% of replicate analysis. Standard drug solution was added to a pre analyzed sample solution and percentage drug content was measured. The results from study of accuracy were reported in table no.3. %Recovery = [(ct –cu)/ ca] × 100. Where ct is the total conc. of the analyte found; cu is the conc. of the analyte present in formulation; and ca is the strength of the pure drug added to the formulation (Table-3).

Precision

Precision (intra-day precision) of the method was evaluated by carrying out the five independent test samples of Aceclofenac. The intermediate precision (inter-day precision) of the method was also evaluated using two divergent analysts, for various days. The percentage relative standard deviation (%RSD) and assay values obtained by two analysts were found to be Good (Table- 4).

RESULTS

Table 1: Optical characteristics and precision of the proposed method

Parameter	value
Absorption maxima (nm)	273.6nm
Beer's law limit (µg/ml)	10-60 µg/ ml
Correlation coefficient (r)	0.9997
Regression equation (Y= mX+c)	Y= 0.043x - 0.002
Slope (m)	0.04318
Intercept (c)	0.00258
Standard Deviation	0.0075
LOD (µg / ml)	1.53
LOQ (µg / ml)	4.63

Table 2: Assay of Aceclofenac tablets

Dosage form	Label claim (mg)	Amount found * ± SD
HIFENAC	100	100.04 ± 0.07211
ACLOPAM	100	99.93 ± 0.055

* An average of three samples for each concentration.

Table 3: Accuracy data of the drug

Sample ID	Concentration µg /ml		(%)Recovery* ± S.D	RSD (%)
	Pure drug drug	Formulation		
80%	40	50	101.3±0.308	0.305
100%	50	50	99.4±0.397	0.40
120%	60	50	99.9±0.222	0.223

* An average of three samples of each concentration

Table 4: Precision of the Aceclofenac working standards

Assay of Aceclofenac as percent of labeled amount		
Sample no	**Analyst –I (Intra-day precision)**	**Analyst –II (Inter-day precision)**
1	100.32	99.78
2	101.32	101.52
3	99.88	100.36
4	100.22	101.24
5	99.98	99.87
Mean	100.34	100.54
%RSD	0.57	0.79

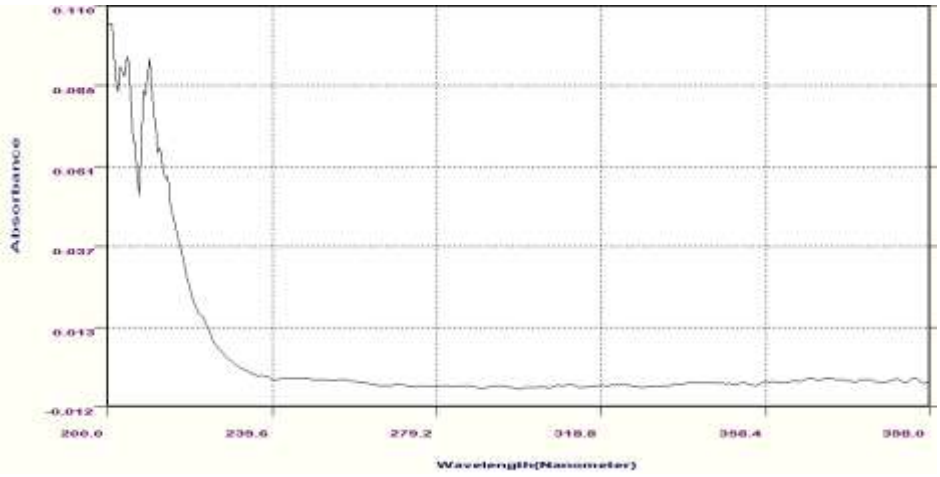

Fig 1: Spectrum of $NaHCO_3$ and Urea

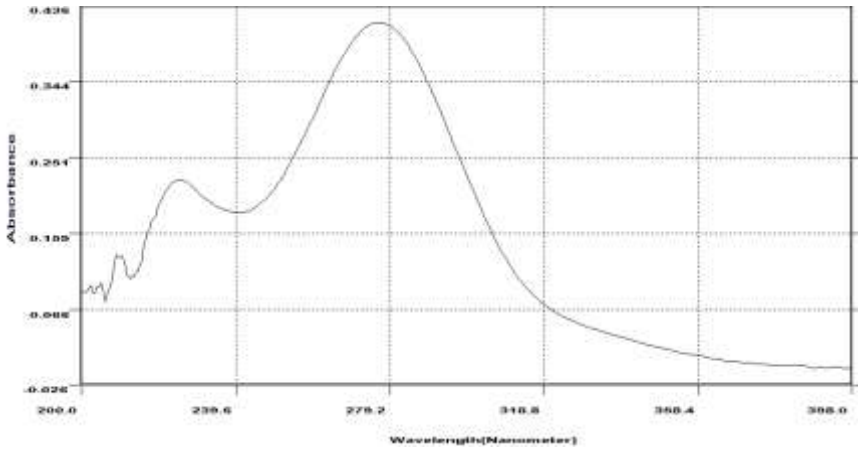

Fig 2: Spectrum of Aceclofenac in $NaHCO_3$ and Urea

DISCUSSION

From the optical characteristics (Table-1) of the proposed method, Aceclofenac was shown its λ max at 273.6 nm in the solvent mixture of hydrotropic agents of 1M urea and 1M sodium bicarbonate with a good correlation coefficient 0.9999. The percentage purity and relative standard deviation from the Assay of the tablet dosage forms (Table-2) were found to be within the limits. The accuracy data of the drug (Table-3) was shown good percentage recovery and %RSD with the range of 99.4 -101.3 and 0.2-0.4 respectively. The Inter-day and Intra-day(Table-4) precision values were found to be 0.57 and 0.79 respectively.

CONCLUSION

The proposed method for the estimation of Aceclofenac was found to be simple, sensitive and reliable with good precision and accuracy. The method is specific while estimating the commercial formulations without interference of excipients and other additives.

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