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Research Article

Simple RP-HPLC method for Aceclofenac quantitative analysis in pharmaceutical tablets

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Abstract

A reverse phase liquid chromatographic method for estimation of Aceclofenac in bulk drug and tablet dosage form was developed and validated. The chromatographic conditions to achieve the highest performance parameters using octylsilyl column with guard filter were optimized. The separation was carried out using a mobile phase containing 10 mM Phosphate Buffer, pH 2.1 and methanol (30:70% v/v) pumped at a flow rate of 1.0 mL/min with detection at 272 nm. The method was shown to be linear in 19.8–148.5 µg/mL concentration range (regression coefficient of 0.999). The limit of detection (LOD) and limit of quantification (LOQ) was found to be 0.0692 µg/mL and 0.2076 µg/mL, respectively. The accuracy of the method was assessed by adding fixed amount of pre-analyzed sample to different standard solutions (80%, 100%, and 120% of the tested concentration) in triplicate. The percentage mean recoveries were 97.91% to 100.39% with %RSD values of 0.64–0.79. The method was found to be precise with %RSD value of 1.13 and 1.60 for intraday and interday precision study, respectively. The method specificity and robustness were also established. New and sensitive HPLC method for estimation of Aceclofenac has been developed, in respect to the reviewed analytical methods.

Keywords

Aceclofenac, Octylsilyl column, 10 mM Phosphate Buffer, Method validation, Robustness

Introduction

Aceclofenac (2-[(2,6-dichlorophenyl)amino]phenylacetoxyacetic acid) is a nonsteroidal anti-inflammatory drug (NSAID) of the phenylacetic acid group. Aceclofenac (ACF) [Fig. 1] selectively inhibit Cyclooxygenase (COX)-2 enzyme to inhibit generation of inflammatory mediators and in turn suppress pro-inflammatory prostaglandins and cytokines production resulting in analgesic, antipyretic activity by both central and peripheral actions (Arslan and Tirnaksiz 2010).

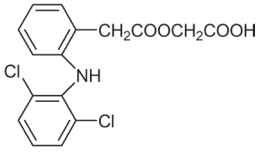

Figure 1. Aceclofenac.

Several methods utilized techniques like HPLC, UV-VIS Spectroscopy, GC, TLC etc. for quantification of ACF have been published as shown in Table 1.

Table 1. Analytical methods of Aceclofenac.

Sl No	Analytical Method	Method Condition/Mobile Phase/ Stationary Phase/Retention Time (Approximately)	Wavelength/ Detector	Linearity Range	Reference
1	HPLC	Methanol and 0.02% of orthophosphoric acid in the ratio of 70:30 (%, v/v); C18; 10 min	275 nm	1–100 µg/mL	Bhinge et al. 2008
2	UV spectroscopy	Phosphate buffer saline of pH 7.4 as diluent	273 nm	0–20 µg/mL	Shah et al. 2008
3	HPLC	Acetonitrile, methanol and water in the ratio of 60:28:12 (%, v/v) and pH of 7.0 adjusted with either glacial acetic acid and sodium hydroxide; C18; 6 min	274 nm	0.0138–0.370 µg/mL	Sherikar et al. 2011
4	HPLC	Acetonitrile, methanol and phosphate buffer of pH 7.0 in the ratio 30:17:53 (%, v/v); C18; 13.8 min	280 nm	2–10 µg/mL	Kumar et al. 2008
5	GC	Injector temperature: 260 °C; Detector temperature: 300 °C; N_2 flow rate: 5.0 mL/min; Make up flow: 30 mL/min; Split ratio: 10:1. Caffeine was used as internal standard (IS)	FID Detector (30 m X 0.53 mm; 1.5 µm)	10–110 µg/mL	Zeng-ri and Fu-jun 2010
6	Spectrophotometric method	Aceclofenac was reacted with 0.25% w/v solution of *p*-dimethyl-aminocinnamaldehyde (PDAC) in 1% v/v perchloric acid solution at 75 °C for 20 min and then diluted with methanol.	665.5 nm	20–100 µg/mL	Zawilla et al. 2002
	HPLC	Methanol, acetonitrile and acetic acid (2% solution in deionized water) in the ratio of 100:150:250 (%, v/v/v) containing 0.3 ml triethylamine; C18; 8.8 min	275 nm	20–70 µg/mL	
	Densitometric method	Chloroform, ethyl acetate and acetic acid in the ratio of 75:25:5, (% v/v/v). Calibration curve is obtained from area under the peak against the concentrations.	254 nm and 275 nm	1–10 µg/spot	
7	Spectrophotometric method	Aceclofenac was reacted with p-dimethylamino-cinnamaldehyde and 1% perchloric acid at 90 °C for 10 min and then diluted with methanol.	658 nm	1–200 µg/mL	Bose et al. 2010
		Aceclofenac was reacted with 3-Methyl-2-benzothiazolinone hydrazine hydrochloride and 0.1% ferric chloride for 20 min and then diluted with water.	592 nm	1–100 µg/mL	
8	HPLC	Sodium phosphate buffer pH 5.0 and Acetonitrile in the ratio of 60:40 (%, v/v); C18; IS: Etoricoxib (ETC); 8 min	275 nm.	25–125 µg/mL	Paul et al. 2011
9	HPLC	Mixed phosphate buffer pH 6.8 and acetonitrile in the ratio of 50:50 (%, v/v); C18; 8.5 min	278 nm	2–10 µg/mL	Ravisankar et al. 2013
10	UV spectrophotometry	Diluent: Methanol	276 nm	0–120 µg/mL	Valambhia 2013
11	Third-derivative spectrophotometry (D3)	Calibration curve was constructed from peak amplitude (height) against corresponding concentration for the linearity range of Aceclofenac solution in methanol.	283 nm	4–24 µg/mL	El-Saharty et al. 2002
	Ratio-spectra first-derivative (RSD1) spectrophotometry	The absorption spectra of Aceclofenac in the linearity range were divided by that of diclofenac sodium (25 mg/mL), and the ratio spectra were differentiated with respect to wavelength. Calibration curve was obtained by plotting the first-derivative values at 252 nm against the corresponding concentration.	252 nm	4–32 µg/mL	
	Spectrodensitometric method of Thin-layer chromatogram	Chloroform, methanol and ammonia in the ratio of 48:11.5:0.5 (%, v/v/v) were used for TLC development. Calibration curve was constructed by plotting the area under the peak against the corresponding concentrations to develop the regression equation.	274 nm	2–10 µg/spot	
12	Third derivative spectrophotometry	UV-spectrum of Aceclofenac solution was measured against absolute ethanol as a blank. The peak height at 242 nm was measured. The calibration curve was constructed with the measured peak height against the corresponding concentration.	242 nm	5–40 µg/mL	Hasan et al. 2003
	Ratio-spectra first-derivative (RSD1) spectrophotometry	Absorption spectra of Aceclofenac solutions were divided by the absorption spectrum of 5 mg/ml of the degradate. The ratio spectra thus obtained were smoothed and differentiated to determine first derivatives of the ratio spectra. The calibration curve was constructed between the measured first derivative values at 245 nm against the corresponding concentration.	245 nm	10–40 µg/mL	
	pH-induced difference (ΔA) spectrophotometry	The difference in absorbance was observed between 0.1 N sodium hydroxide and 0.1 N hydrochloric acid solution of Aceclofenac. Calibration curve was constructed by plotting the difference in absorbance against respective concentration.	273 nm	15–50 µg/mL	
	Quantitative densitometric evaluation of thin layer chromatogram	Tetrahydrofuran and methanol (90:10, % v/v) was used for TLC development. Calibration curve was constructed by plotting the area under the peak against the corresponding concentrations.	275 nm	50–200 µg/mL	
	HPLC	Methanol and water in the ratio of 60:40 (%, v/v); C18; 8 min	230 nm	1–50 µg/mL	
13	HPLC	0.01 M ammonium acetate buffer with 2 ml (%, v/v) triethylamine and acetonitrile in the ratio of 68:32 (%, v/v) and pH was adjusted to 6.5 with glacial acetic acid; C8; 6.5 min	270 nm	8–16 µg/mL	Chatrabhuji et al. 2015
14	HPLC	0.07% of orthophosphoric acid and acetonitrile in the ratio of 68:32 (%, v/v) at pH 7.0 ± 0.05; C18; 6 min	275 nm	160–240 µg/mL	Hossain et al. 2013
15	Microwave assisted spectrophotometry	Aceclofenac was reacted with ammonium molybdate in presence of sulfuric acid under microwave irradiation for 5 min.	740 nm	50–250 µg/mL	Mumtaz et al. 2013

Moreover, several HPLC methods for simultaneous estimation of ACF in present of other active constituents have been established as summarized in Suppl. material 1: Table S1. In respect to these findings a new specific HPLC method for rapid, accurate and precise estimation of ACF in bulk drug and in pharmaceutical dosage form has been developed.

Experimental

Instruments

All weighing were done on Electronic balance (A & D Company Ltd, Japan). Digital pH meter (SENSION+, Spain), bath sonicator (Wisd Laboratory Instrument,

Table 2. Placebo Constituents.

Lactose	:	480 mg
Microcrystalline cellulose	:	500 mg
Sodium Starch Glycolate	:	200 mg
Povidone K-30	:	125 mg
Magnesium Stearate	:	100 mg
Talc	:	100 mg

Germany) were also used in this study. UV-Vis spectra were recorded on a Specord 250 plus PC double beam spectrophotometer using 1.0 cm quartz cells. High purity deionized water was obtained from Millipore, Milli-Q (Merck KGaA, Darmstadt, Germany) water purification system. Assay test was performed with a HPLC (Hitachi High – Tech Science Corporation, Tokyo, Japan) machine with pump (Hitachi chromaster 5110), autosampler (Hitachi chromaster 5210) and PDA Detector (Hitachi chromaster 5430). LC separations were performed on a C8 column (250 × 4.6 mm i.d., 5 µm particle size), LaChrom, Hitachi, Japan with C8 guard column (23 mm X 4 mm; 3 µm), LaChrom, Hitachi, Japan. Data was integrated using Agilent open lab control panel CDS software. The mobile phase consisted of 10 mM Phosphate Buffer, pH 2.1 and methanol in 40:60%, v/v. The flow rate was set to 1.0 mL/min and UV detection was carried out at 272 nm at 25 °C.

Reagents

The 0.25-µm PTFE filters were obtained from Chromafil Xtra (Macherey Nagel GmbH & Co. AG., Germany). Working standards of pharmaceutical grade ACF (batch no. 28296) was supplied as a gift sample by Beximco Pharmaceutical Ltd (Dhaka, Bangladesh). Marketed ACF 100 mg tablets (Square Pharmaceuticals Ltd.) were purchased from local drug store. All chemicals and reagents of analytical grade were purchased from Active Fine Chemicals, Dhaka, Bangladesh.

Buffer Preparation

10 mM phosphate buffer was prepared by dissolving 0.64 gm potassium dihydrogen phosphate and 0.4 mL phosphoric acid to 900 mL deionized water. pH of the solution was adjusted to 2.1 with dilute phosphoric acid solution if necessary. The final volume was then adjusted to 1000 mL with deionized water.

Placebo preparation

Commonly used excipients were mixed at appropriate amount to obtain the placebo mixture as Table 2. Placebo stock solution was prepared by mixing average tablet placebo content with mobile phase to obtain concentration of approximately 1.5 mg/mL.

Method Optimization

Stock solution of ACF was prepared in methanol (≈50 µg/mL) and the UV spectrum was taken in the range of 200–400 nm to obtain the wavelength for maximum absorbance (λ_{max}) of Aceclofenac. As Aceclofenac (pKa≈3.4) is a strongly acidic drug, pH 2.1 was chosen as the buffer pH for mobile phase preparation. Mobile phase was taken as 10 mM phosphate buffer of pH 2.1 and methanol in the ratio of 30:70 (%, v/v). Solvent stability was checked at approximately 100 µg/mL concentration for consecutive five days in the mobile phase by determining the relative standard deviation (%RSD) of response and peak purity of the drug. The described method has been validated for response function, accuracy, repeatability and intermediate precision.

Standard and Sample preparation

Standard stock solution at 1 mg/mL concentration was prepared in mobile phase by dissolving it first on not more than 5% of methanol. Sample stock solution was prepared by crushing randomly selected 10 tablets. Average weight equivalent sample was taken in volumetric flask to obtain concentration of approximately 1 mg/mL. Sample was also first dissolved in not more than 5% of methanol. The final volume was adjusted with mobile phase. The concentration for assay preparation was approximately 100 µg/mL. Drug content was determined using Equation 1.

$$\text{Drug content (mg/tablet)} = \frac{\text{sample peak area}}{\text{standard peak area}} \times \frac{\text{standard weight (mg)}}{\text{sample weight (mg)}} \times \text{avarage weight (mg)} \times \frac{\text{Potency of standard(\%)}}{100} \quad \text{(Eq. 1)}$$

Linearity

The linearity of the method was established by determining linear regression equation from the calibration curve of ACF. The calibration curve was prepared using six different concentration levels in triplicate ranging from 20% to 150% of the assay preparation of analyte. For this, a stock solution (1 mg/mL) of the drug was prepared in mobile phase using not more than 5% of methanol initially. A range of concentrations (19.8–148.5 µg/mL) were then prepared after suitable dilution of the prepared stock with mobile phase.

LOD and LOQ

LOD and LOQ were separately determined based on the signal to noise ratio as per ICH guidelines (ICH Q2 R1. 2005).

Accuracy

Accuracy of the method was determined by performing the recovery experiment of standard addition method at three concentration levels in triplicate (Chakraborty et al. 2018). Different amount of standard stock solution was taken at 80% to 120% of assay concentration and mixed with

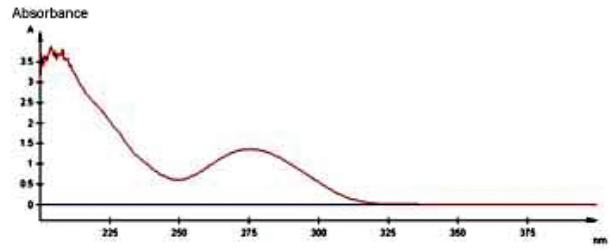

Figure 2. Absorbance maxima of Aceclofenac.

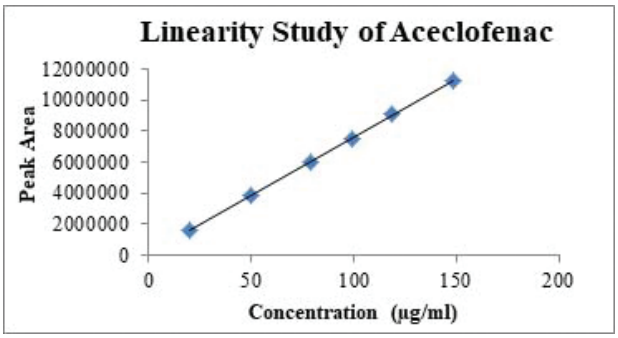

Figure 3. Calibration curve of linearity Study.

fixed amount of previously analyzed sample stock solution of 1 mg/mL concentration to obtain final concentration of approximately 101–140 µg/mL.

Precision

Repeatability

The precision of the instrument (RSD) was checked by repeated scanning of samples (n = 6) for ACF standard without changing the parameter of the proposed method.

Intermediate precision

To determine the intra-day and inter-day precision of the method, the drug solution at assay concentration (100 µg/mL) was prepared (n = 6) in one laboratory on the same day (1st, 3rd, and 6th hour) and also on five different days from the same standard stock solution. The concentration was calculated from the areas obtained and the results were expressed as relative standard deviation (%RSD).

Specificity

Specificity was determined by checking the chromatograms of blank, placebo, standard and sample solution for interference with analyte peak, as well as through determination of peak purity for the drug in the presence of degradation products.

At first different placebo concentration were spiked with nominal concentration of drug substance and then different concentration level of drug were spiked with fixed placebo concentration to determine the peak response (Chakraborty et al. 2018). The responses of the standard ACF, marketed product and excipient of stressed condition (kept at 80 °C for 48 hrs) were also compared with the response of the same samples of unstressed condition at the assay concentrations to establish the stability indicating nature of the developed method as part of the forced degradation studies.

Table 3. Evaluation of linearity, Limit of Detection (LOD) and Limit of Quantitation (LOQ).

$\lambda_{max.}$ (nm)	Regression equation (y = mx + c)	Linearity range (µg/mL)	Residual sum of squares	Correlation coefficient	Baseline Noise in rms	S/N for LOD	S/N for LOQ
275	74894x + 94097	19.8 to 148.5	2.213	0.999	218.7	3.005	9.36

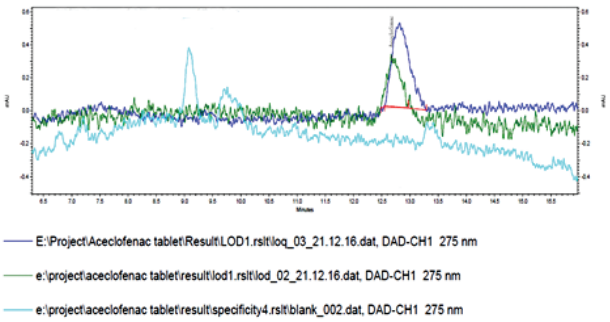

Figure 4. Sensitivity Study.

Robustness

Robustness was determined by changing the different method parameters like mobile phase composition, pH of buffer, column temperature, mobile phase flow rate and detector wavelength.

System Suitability

Six replicate injection of ACF standard solution at assay concentration was checked for tailing factor, theoretical plate, retention time, capacity factor and relative standard deviation of response to establish suitability of the method in the instrument.

Results and discussion

The wavelength for maximum absorbance of ACF was found to be at approximately 275 nm (Fig. 2).

Marketed tablets were analyzed through the developed method which showed 101.78% of ACF with 0.186 of %RSD. The proposed method was found to be linear with a correlation coefficient of 0.999 (Table 3 and Fig. 3).

The baseline noise value was obtained from the software (Table 3). The minimum concentration levels at which ACF can be reliably detected (LOD) and quantified (LOQ) were found to be 0.0692 µg/mL and 0.2076 µg/mL respectively (Fig. 4 and Table **3**) which was more sensitive

Table 4. Evaluation data of accuracy study.

Level	Theoretical Conc. (µg/mL)	Peak area	Actual Conc. (µg/mL)	% Recovery	% RSD
80%	101.16	7553140	100.64	99.48	0.64
	101.16	7618998	101.52	100.36	
	101.16	7525643	100.28	99.13	
100%	121.36	8984771	119.72	98.65	0.66
	121.36	8917608	118.83	97.91	
	121.36	9034943	120.39	99.2	
120%	141.55	10664687	142.11	100.39	0.79
	141.55	10737296	143.07	98.94	
	141.55	10644064	141.83	100.2	

Table 5. Evaluation data of precision study.

Sample No.	Repeatability	Intermediate Precision			
		Intra – day		Inter – day	
1	102.83	1st hour	102.57	1st day	103.70
2	99.86	3rd hour	101.40	2nd day	101.22
3	101.73	8th hour	102.68	3rd day	102.53
4	102.48	–	–	4th day	99.86
5	101.73	–	–	5th day	103.59
6	101.69	–	–	–	–
Mean	101.721		102.216		102.181
SD	1.025		0.579		1.464
%RSD	1.007		0.567		1.432

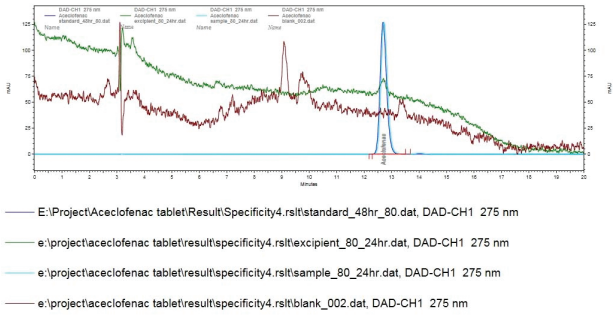

Figure 5. Specifity study-response of the standard, sample, excipient and mobile phase.

Table 6. Assay at Accelerated State of 80 °C.

	Concentration (%)			
	Initial	8 hour (80 °C)	24 hour (80 °C)	48 hour (80 °C)
Standard :	100.16	100.72	103.28	103.13
Sample :	96.18	100.49	97.81	97.48

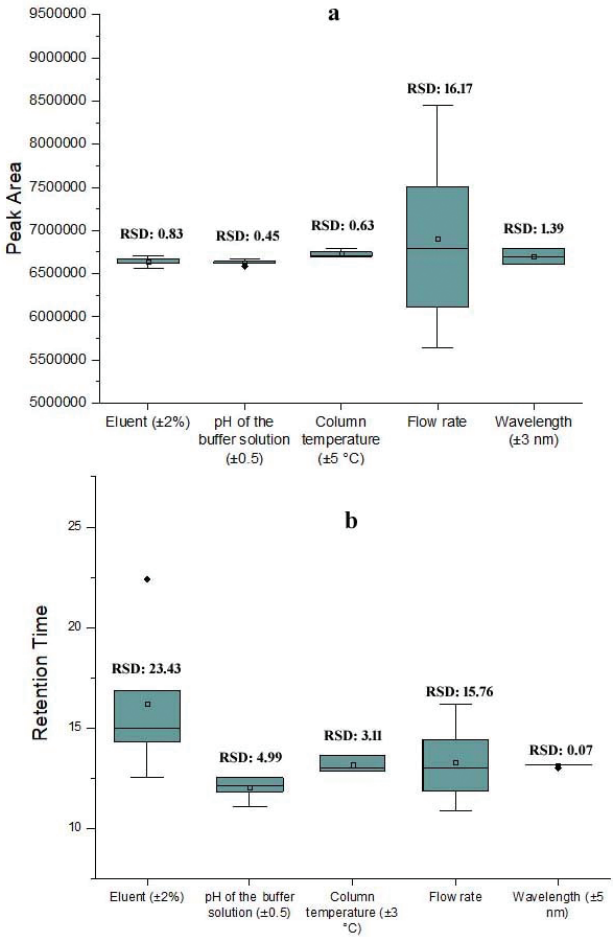

Figure 6. Robustness Study (a) Variance of peak area for change in different method parameters with %RSD; (b) Variance of Retention time for change in different method parameters with %RSD. *Method was robust for change in pH of mobile phase (±0.5), wavelength (±3 nm) and column temperature (±3 °C).

than some of the other published methods (Ravisankar et al. 2013, Balan and Kannappan 2014). Signal to noise (S/N) ratio for LOD and LOQ was shown in Table 3 which was also within acceptable limits.

The mean recoveries were 97.91% to 100.39% substantiated the method as accurate (Table 4). The method was also found to be precise with <2% of RSD value (Table 5) for both repeatability and intermediate precision study.

The developed analytical method should be specific for ACF assay in presence of all the potential matrix components which was checked by evaluating the peak responses and peak purity of the standard, sample, excipient and mobile phase (blank) solutions in assay concentration (Fig. 5). Specificity of the proposed method is also evaluated by the stress study of the samples. The % assays of ACF standard and marketed product were unaffected by the stressed condition as compared to the initial result at different observation days (Table 6). So the placebo effect was checked in peak response as described in the method. The response obtained with the mixture showed no interference with the standard response (Table 7).

The change in organic solvent of ±2% [Buffer/68–72(%, v/v) Methanol] significantly changed the peak retention time from 22.40–12.41 min, although the %RSD of the peak response was found to be 0.83. The method was found to be robust for pH variation of the buffer solution from 1.7 to 2.5 (%RSD of 0.45 for the peak response), although the retention time (R_t) changed from 11.09 to 12.52 min. For the change in column temperature from 20–25 °C the retention time changed from 14.23–12.27 min with acceptable %RSD (0.63) of the peak response.

Table 7. Specifity study of Aceclofenac-standard spiked with excipients.

Fixed drug substance spiked with different concentration of excipient			Fixed excipient spiked with different concentration of drug substance		
Nominal drug substance concentration (µg/mL)	Excipient concentration (µg/mL)	Absorbance	Nominal excipient concentration (µg/mL)	Drug substance concentration (µg/mL)	Absorbance
87.693	128.72	6705872	160.9	70.154	5428265
	144.81	6664433		78.923	5898186
	160.9	6707371		87.693	6873075
	176.99	6784787		96.462	7506926
	193.08	6805847		105.231	8074567
RSD = 0.881%			Regression equation, y = 78699x - 145122 R^2 = 0.9892		

Flow rate of mobile phase was changed from 0.8 to 1.2 mL/min. The R_t and peak response of ACF both changed significantly for change of flow rate from 0.9 to 1.1 mL/min. Robustness of the method was checked for change in wavelength from 270–280 nm. The method was found to be robust for 272–278 nm with %RSD of 1.39 for peak response. The method conditions at which response were most stable was shown in Fig. 6.

Conclusion

In this study a simple RP-HPLC-DAD method for use in routine estimation of ACF in bulk drug and tablet dosage form has been developed and validated. The accuracy, precision and specificity of the method have been established, with determination of the method parameters up to which the method was found to be stable.

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Supplementary material 1

Table S1. HPLC Analytical methods for simultaneous estimation of Aceclofenac with other constituents

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Data type: HPLC Analytical methods

Explanation note: Comparision of published simultaneous HPLC analytical method of Aceclofenac with other drugs.

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