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NOTE

Reversed-Phase HPLC Determination of Aceclofenac in Bulk Powder and its Pharmaceutical Tablets

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This paper presents a simple accurate, reproducible and rapid RP-HPLC method for estimation of aceclofenac in both bulk powder and its tablet. The analysis was carried out, in isocratic mode, on C18 column. The mobile phase is comprised of acetonitrile: methanol:phosphate buffer pH 7.0 (30:17:53). A stock solution of 1 mg/mL of aceclofenac in mobile phase was prepared and the linearity over a range of 2-10 mcg/mL was examined. The retention time of the drug was 13.8 min. The R^2 value of 0.9992 indicates a good linearity in the concentration range of 2-10 mcg/mL. The chromatogram was scanned at 280 nm, which is the absorption maximum of the drug.

Key Words: Aceclofenac, RP-HPLC.

Aceclofenac, a synthetic NSAID used in the treatment of rheumatoid arthritis and osteoarthritis[1]. Chemically, it is {O-(2,6-dichloroanilino) phenyl}acetate glycolic acid ester (Fig. 1). It is official in BP[2], Martindale extra pharmacopoeia[3], European pharmacopoeia[4] and Merck index[5]. It is available commercially in the form of tablets. The literature survey reveals titrimetric[4], spectrofluorimetric[6] and UV spectrophotometric[7] methods for its estimation. This paper presents a simple, accurate, reproducible and rapid RP-HPLC method for estimation of aceclofenac in both bulk powder and its dosage forms using KNAUER-CHEMITO HPLC system.

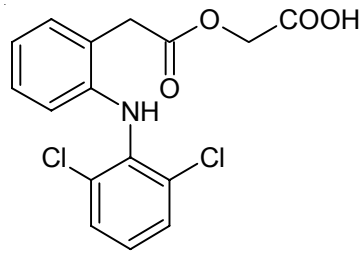

Fig. 1. (2-{2-[(2,6-dichlorophenyl)amino]phenyl}acetoxy)acetic acid

HPLC system consisted of Dual Pump (Knauer K-501), 20 µL loop Knauer injector and Chemito LC 6500 UV-Vis Detector. The analysis was carried out, in isocratic mode, on Eurosphere-100 C18, column (250 mm × 4.5 mm ID, 5 µm) (Knauer, Germany). The data was recorded using Chemitochrome 2000 software.

IR spectra were recorded on Shimadzu FTIR 8400S equipped with DRS 8000. All weighings were done on Precisa XB 120A. Solvents used were of HPLC grade (Merck) and chemicals used were of AR grade. Solvent and sample solutions were filtered using 0.45 and 0.2 micron membrane filters respectively prior to use.

ACL used as standard was confirmed by FTIR and the purity estimated as 99 % using reported method[7].

20 Intact tablets of ACL were weighed to obtain the average weight of the tablet. They were then crushed to a fine powder in a mortar. An amount of the powder equivalent to the average tablet weight was weighed accurately into a 100 mL volumetric flask, dissolved well and made upto with the mobile phase consisting of acetonitrile:methanol:phosphate buffer pH 7.0 (30:17:53) and filtered. 1 mL of the resulting filtrate was diluted accordingly with mobile phase. 20 µL of the solution was injected and the chromatogram recorded.

Optimization of mobile phase: Optimization of mobile phase was done for effective determination. The column was equilibrated with the mobile phase for 0.5 h prior to analysis. The flow rate was adjusted to 1 mL/min and the detection was done at 280 nm.

Preparation of calibration curve: A stock solution of 1 mg/mL of ACL in mobile phase was prepared and the linearity over a range of 2-10 mcg/mL was examined.

Under the proposed chromatographic conditions, the retention time of the drug was 13.8 min. The R^2 value of 0.9992 indicates a good linearity in the concentration range of 2-10 mcg/mL. The chromatogram was scanned at 280 nm, being the absorption maxima of ACL. The assay value and recovery data indicate that the method is free from interference of excipients. The concentration indicates that the method is in accordance with Beer's law over this range (Table-1). The sample solution was found to be stable for a period of one week at room temperature.

The accuracy, reproducibility and precision of the method were established by spiking a sample solution containing known amount of standard drug (Table-2). Hence the simple and reproducible method can be effectively used for routine analysis.

TABLE-1
OPTICAL CHARACTERISTICS

Parameters	Values	
λ_{max}	280 nm	
Beer's law limit	2-10 mcg/mL	
Regression equation	y = 292.85x - 13.851	
Slope	281.3 to 304.4	
Intercept	Y-intercept when X=0	-84.01 to 56.31
	X-intercept when Y=0	0.1988 to 0.2779
Correlation co-efficient R^2	0.9992	
Recovery (%)	98.6	

TABLE-2
RECOVERY STUDIES

Claim (mg)	Found* (mg)	Recovery (%)
100	98	98
100	99	99
100	99	99

*Average of three determinations.

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