

## RP-HPLC Method Development and Validation of Zaltoprofen in Pure Form and in Pharmaceutical Formulation

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### Abstract

A simple, rapid, sensitive and precise RP-HPLC method has been developed for the estimation of zaltoprofen in tablet dosage form. In this method Phenomenax Luna C18, 250 x 4.6 mm, 5µm column with mobile phase consisting of acetonitrile and 0.02 M phosphate buffer in the ratio of 50:50 v/v in isocratic mode was used. The detection wavelength is 232 nm and the flow rate is 1.2 mL/min. The method is linear in the concentration range of 20-120 µg/mL. The linearity of zaltoprofen shows a correlation coefficient of 0.999. The percentage recovery ranges from 99.82-100.46 %. The proposed method was validated by determining linearity, accuracy, precision, specificity, LOD and LOQ.

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### INTRODUCTION

Zaltoprofen, 2 - (10, 11 - dihydro - 10 - oxodibenzo [b, f] thiepin - 2 - yl) pro-pionic acid is a potent non-steroidal anti-inflammatory drug (NSAID) [1]. It is a preferential COX-2 inhibitor, exhibited a potent inhibitory action on the nociceptive responses induced by a retrograde infusion of bradykinin into the right common carotid artery in rats [2]. The drug can be estimated by HPLC in plasma [3-7]. There is a chiral HPLC method for enantioselective analysis [8],

Stability-Indicating LC method in bulk drug and formulations [9] and a spectrophotometric method [10]. The present work aims to develop a simple sensitive, precise and accurate RP-HPLC method for the determination of zaltoprofen in pure form and in tablets.

## EXPERIMENTAL

### Instrumentation

Waters 2695 HPLC system equipped with Phenomenax Luna C18, 250 x 4.6 mm, 5µm column, Rheodyne injector with 10 µL loop, 2996 PDA detector and Empower-2 software was used.

### Reagents and chemicals

Pottasium dihydrogenorthophosphate of analytical grade, HPLC grade milli-Q water and acetonitrile were used. Zaltoprofen was a gift sample from Baif Laboratories Ltd. India. The tablets of Zaltoprofen were obtained from local pharmacy.

### Preparation of buffer

1.36 gm of potasium dihydrogen orthophosphate was weighed accurately and dissolved in 500 ml of HPLC grade water and pH was adjusted to 5.5 by ortho-phosphoric acid solution.

### Chromatographic conditions

The separation was carried out by Phenomenax Luna C18, 250 x 4.6 mm, 5µm column with the solvent system (mixture of 0.02 M phosphate buffer and acetonitrile in the ratio of 50:50 % v/v) at 30°C. The flow rate was maintained at 1.2 ml/min. The column outlet was monitored at 232 nm. The injection volume was 10 µL and run time was 10 min.

### Preparation of Standard solution

Pure zaltoprofen (100 mg) was weighed accurately and transferred in to a clean 100 mL volumetric flask. The content was dissolved by using HPLC grade methanol (70 ml), after complete dissolution the volume was made up to the mark by using the HPLC grade methanol which gives 1000 µg/mL of the zaltoprofen.

### Linearity

The standard zaltoprofen solution was further diluted in 10 mL volumetric flask to get various concentrations ranging from 20 to 120 µg/mL of drug using mobile phase. From this each calibration standard solutions 10 µL was injected in to the HPLC system. The chromatograms were recorded. The concentration of the zaltoprofen (µg/mL) is taken in X axis and peak area of various standard solutions was taken in Y axis. The linearity graph was plotted.

### Estimation in pharmaceutical formulation

Twenty tablets (zaltoprofen) weighed accurately; average weight was calculated and crushed to get fine powder. Powder equivalent to 80 mg of zaltoprofen was weighed accurately and transferred into a 100 mL volumetric flask containing little amount of mobile phase and sonicated for 20 min for complete dissolution of drug. The volume was made up to 100 mL with mobile phase and the solution was filtered through 0.45 µm membrane filter. The solution was suitably diluted with mobile phase to produce suitable concentration and analysed by injecting six times into the HPLC system. The peak area was recorded and amount in tablets estimated from linearity graph.

## RESULTS AND DISCUSSION

The system suitability studies were carried out to determine column efficiency, retention time, peak area of single standard solution and peak asymmetry (Table 1). The drug was eluted at 3.7 min and a typical chromatogram for standard is in figure 1. Typical chromatograms for blank and sample are in figure 2 and 3 respectively.

**Table1:** System suitability data

Drug	USP Plate Count	Tailing factor (T)	Retention time (min), (n=6)		Peak area, (n=6)	
			Mean± S.D	%RSD	Mean± S.D	%RSD
Zaltoprofen 80 µg/mL	7248	1.34	3.75± 0.0526	1.3989	1578511± 6866	0.4350

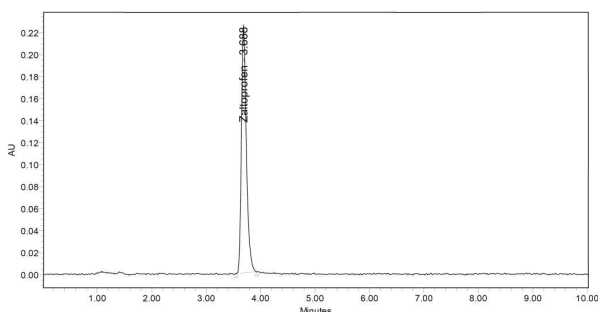
**Table 2:** Linear regression data for calibration curve

Parameters	Values
Concentration range, µg/mL	20- 120
Slope	20704.16
Intercept	-57003.33
Correlation coefficient	0.999

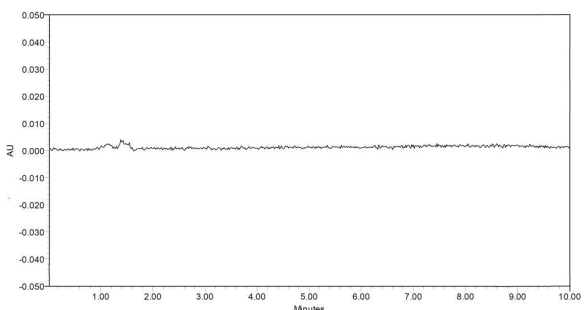
**Table 3:** Assay results, precision and recovery studies

Formulation	Labeled amount (mg/tab)	(% label claim* ± S.D)	% Recovery	Precision (% RSD)	
				Inter-day (n=24)	Intra-day (n=6)
Zaltoprofen tablets	80	99.998 ± 0.0259	99.82 % to 100.46 %	0.3548	0.0259

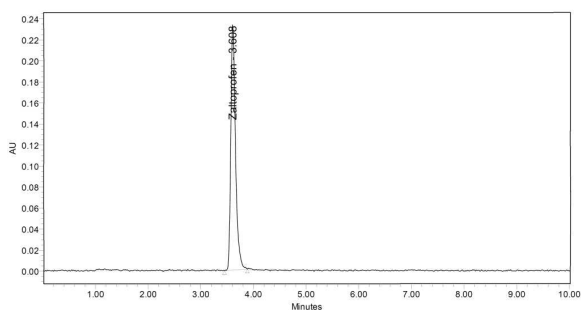
\* Average of six determinations.



**Figure 1:** A typical chromatogram of Zaltoprofen standard solution.



**Figure 2:** A typical chromatogram of Blank



**Figure 3:** A typical chromatogram of Zaltoprofen sample solution

The concentration range from 20-120 µg/mL of drug the method showed linear response with the correlation value of 0.999 (Table 2). The accuracy of the method was determined by recovery studies; the percentage of recovery was calculated and the result shows (Table 3) that the method has no interference from the additives used for the formulation. The precision of the developed method was confirmed by performing inter day and intraday assay, %RSD was calculated (Table 3). The developed method was applied to estimate zaltoprofen from the pharmaceutical formulation and assay results are shown in table 3. The limit of detection (LOD) and the limit of quantification (LOQ) were 0.1864 µg/mL and 0.5649 µg/mL respectively.

## CONCLUSION

The proposed HPLC method is simple, selective, accurate, precise, linear and rapid. Hence this method can be applied for the quality control of zaltoprofen in pure as well as in pharmaceutical preparations.

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