

## ANALYTICAL METHOD FOR DEVELOPMENT OF CEFETAMET PIVOXIL HYDROCHLORIDE IN BULK AND SINGLE COMPONENT FORMULATION

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**ABSTRACT**

Two simple, precise and economical UV method have been developed for estimation of Cefetamet Pivoxil Hydrochloride in bulk formulation. Cefetamet Pivoxil Hydrochloride has the absorbance maxima in zero order spectra at 260nm (Method A). Method B applied was First order derivative for the analysis of Cefetamet Pivoxil Hydrochloride at 241nm. Drug followed Beer-Lambert's law in the concentration range of 10-90µg/ml for zero order and 10-70µg/ml for first order derivative spectrum. Results of analysis were validated statistically and were found to be satisfactory.

**KEY WORDS:** Cefetamet Pivoxil Hydrochloride, Zero order spectra, First order derivative, UV Spectrophotometer.

**INTRODUCTION**

Cefetamet is a new bitter Cephalosporin with a broad-spectrum activity against many aerobic gram-positive and gram-negative organisms. It is more active than current oral cephalosporin against many members of the family Enterobacteriaceae. The ester of this drug is rapidly converted to Cefetamet by esterases during its first passage through the gastrointestinal mucosa or liver. Cefetamet pivoxil was effective in the treatment of otitis media, pneumonia, pharyngotonsillitis and urinary tract infections in children.

It is not official in any of the Pharmacopoeias but it is listed in Merck index<sup>1</sup> and Martindale, the complete drug reference<sup>2</sup>. Literature survey as indicated that there is analytical method for estimation of Cefetamet pivoxil hydrochloride single component by UV-Visible Spectrophotometry but there are few other methods which are reported like, RP-HPLC method<sup>3</sup>, validated Kinetic Spectrophotometric in commercial dosage form<sup>4</sup>, Synchronous spectrofluorometric determination of cefetamet pivoxil hydrochloride in powder and bulk dosage forms<sup>5</sup>, Spectrophotometric estimation of cefetamet pivoxil hydrochloride in dosage forms<sup>6</sup>, HPLC-UV method<sup>7</sup>, HPTLC method<sup>8</sup>, LC method for estimation of Cefetamet in tablets<sup>9</sup>.

In presence study, we developed simple, precise, accurate, sensitive, rapid and economical UV-Visible Spectrophotometric method for estimation of Cefetamet in bulk and formulation.

**MATERIALS AND METHODS**

**Materials**

Pure Cefetamet Pivoxil Hydrochloride was obtained as a gift sample from ALEMBIC Ltd. Naroda, Ahmedabad. A Shimadzu UV-1700 UV/VIS Spectrophotometer was used with 1cm matched quartz cells. CEFETAMET tablets of 250mg strength were procured from local pharmacy.

**Method**

Accurately about 10 mg of Cefetamet Pivoxil Hydrochloride was weighed and transferred to 100 ml volumetric flask. To it 40 ml of ethanol was added, to dissolve the drug completely with vigorous shaking, then the volume was made up with distilled water up to the mark to give the drug stock solution of concentration 100 µg/ml. Aliquots of standard stock solution were pipette out and suitably diluted with distilled water to get final concentration of standard solutions. In zero order spectrum method, at n=6 showed a sharp peak at 260nm (Figure 1). The absorbance difference at n=6(dA/dλ) is calculated by the inbuilt software of the instrument which was directly proportional to the concentration of the standard solution. The standard drug solution was diluted so as to get the final

concentration in the range of 10-90µg/ml and scanned in zero order spectra. The calibration curve of dA/dλ against concentration of the drug showed linearity.

Similarly, for first order derivative, same method was employed at n=1 showed a sharp peak at 241nm (Figure 2). The standard drug solution was diluted so as to get the final concentration in the range of 10-70µg/ml and scanned in first order derivative spectra. The calibration curve of dA/dλ against concentration of the drug showed linearity.

For estimation of Cefetamet Pivoxil hydrochloride in tablet formulation by the two methods, twenty tablets of the marketed brand were weighed and triturated to fine powder. Tablet powder equivalent to 10mg of Cefetamet Pivoxil Hydrochloride was weighed and transferred to 100 ml volumetric flask and dissolved in 20 ml of methanol. It was kept for ultrasonification for 45 min, finally the volume was made up to the mark with distilled water, this was then filtered through Whatman filter paper no. 41 to get tablet stock solution of concentration of 100 µg/ml. Various dilution of the tablet solution were prepared and analysed for six times and concentration was calculated by using calibration curve for both methods.

Both the methods were validated according to ICH guidelines<sup>10,11</sup> by carrying out analysis of six replicate samples of the tablets (Table 1) recovery studies were carried out at three different levels i.e. 80%, 100% and 120% by adding the pure drug (8, 10 and 12 mg respectively) to analysed tablet powder sample. From the amount drug found, percentage recovery was calculated (Table 2).

**RESULT AND DISCUSSION**

Both the methods A and B, for estimation of Cefetamet pivoxil hydrochloride in tablet dosage form were found to be simple, accurate and reproducible. Beer-Lambert's law was obeyed in the concentration range of 10-90µg/ml for zero order and 10-70µg/ml for first order derivative spectra. The value of standard deviation was satisfactory and the recovery studies were close to 100%.

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**Table 1: Optical characteristics and other parameters for Cefetamet pivoxil hydrochloride**

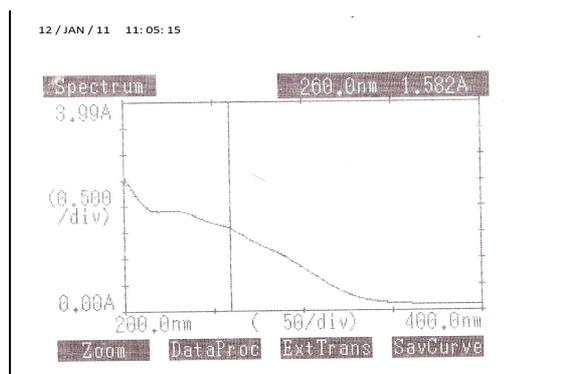
PARAMETERS	METHOD A	METHOD B
$\lambda_{max}$ (nm)/wavelength range (nm)	260	241
Beer's-Lamberts range ( $\mu\text{g/ml}$ )	10-90	10-70
Coefficient of Correlation ( $r^2$ )	0.9991	0.9992
Regression Equation: $Y=mx+c$		
a. Slope (m)	0.0198	0.0232
b. Intercept (c)	0.0129	0.0031
LOD	87.06	0.7396
LOQ	263.83	2.241
Molar Absorptivity	$115.5 \times 10^8$	$108.85 \times 10^7$

A is zero order spectrum method with n=1  
 B is first order derivative spectrum method with n=1  
 T<sub>1</sub> and T<sub>2</sub> is the brand of tablet formulation

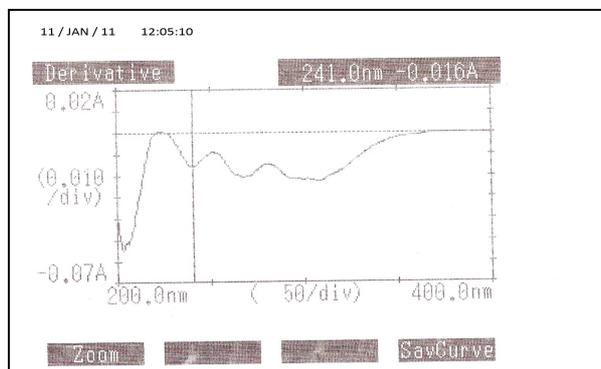
**Table 2: Analysis of standard Cefetamet pivoxil hydrochloride**

Method	Tablet Formu.	% Mean	S. D.*	C. O. V.	S. E.
A	T <sub>1</sub>	99.98	0.6524	53.92	0.185
	T <sub>2</sub>	100.06	0.2597	0.2595	0.106
B	T <sub>1</sub>	100.05	0.8792	0.0084	0.0452
	T <sub>2</sub>	99.79	0.4527	0.4536	0.1848

A is zero order spectrum method with n=1  
 B is first order derivative spectrum method with n=1  
 T<sub>1</sub> and T<sub>2</sub> is the brand of tablet formulation



**Figure 1: Zero order spectrum of Cefetamet pivoxil hydrochloride**



**Figure 2: First order derivative spectrum of Cefetamet pivoxil hydrochloride**

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