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Ultra Violet Spectrophotometric determination of Keterolac Tromethamine in pharmaceutical dosage forms

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ABSTRACT

A U.V. spectrophotometric method is developed for the quantitative estimation of Keterolac Tromethamine in pharmaceutical dosage forms. The present method is simple, accurate, economical and reproducible for the estimation of Keterolac Tromethamine in pharmaceutical dosage forms. The solutions are prepared in acidic methanol solvent. Maximum absorbance is observed at 316 nm and measurements were made at 316 nm wavelength. Beer's law is obeyed and linearity is observed in the concentration range of 2.5 – 15 µg/mL. The correlation coefficient is found to be 0.9999. The % recovery was 99.23 – 99.48%. This method is validated as per ICH guidelines and the results were with in the limits. The present U.V. Spectrophotometric method is accurate, simple, sensitive, economical and reproducible for the estimation of Keterolac in pharmaceutical dosage forms.

Keywords: U.V. Spectrophotometry, Absorbance, U.V. Spectra, Keterolac Tromethamine, Pharmaceutical dosage form.

INTRODUCTION

Keterolac Tromethamine is chemically 5-Benzoyl-2, 3 dihydro-1H Pyrrolizine-1 carboxylic acid compound with 2-amino -2 (hydroxy methyl)-1, 3 propane diol. Its molecular formula is $C_{19}H_{24}N_2O_6$, molecular weight is 376.44. Keterolac is a non-steroidal anti-inflammatory drug in the family of heterocyclic acetic acid derivative, often used as an analgesic, antipyretic and anti-inflammatory agent. It is available as "Toradol" tablets in the market and each tablet contains 10 mg Keterolac Tromethamine. The chemical structure of Keterolac Tromethamine is shown in Fig.1. The U.V. Spectra of Keterolac Tromethamine is shown in Fig.2.

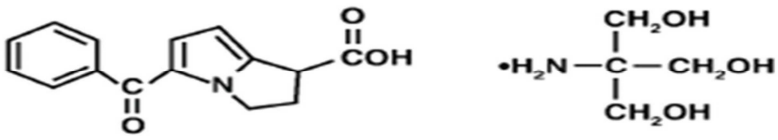

Fig.1. Chemical structure of Keterolac Tromethamine

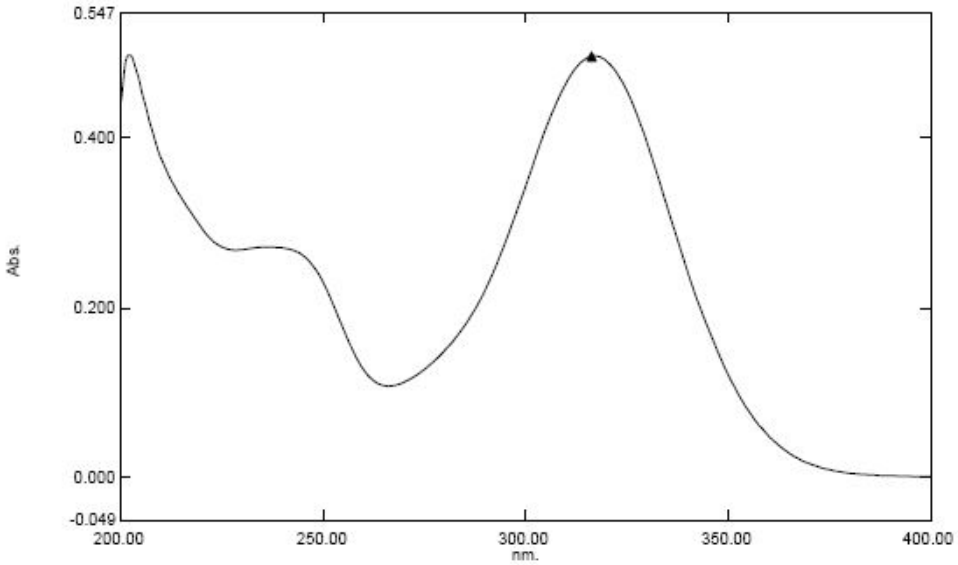

Fig.2 The U.V. Spectra of Keterolac Tromethamine

As per literature survey , keterolac tromethamine was determined by RP-HPLC,HPTLC methods [1-7] . It was also determined by spectrophotometric methods through complexation ,Charge transfer and ion-pair formation[8,9].Simultaneous determinations with other drugs by spectrophotometric methods have also been developed [11-18].Even though ,there are several visible spectrophotometric methods available in the literature, no UV Spectrophotometric method is reported for the estimation of Keterolac Tromethamine alone in pharmaceutical dosage forms and hence the authors report a simple accurate, precise, economic and reproducible U.V. Spectrophotometric method for the estimation of Keterolac Tromethamine .

EXPERIMENTAL SECTION

Instruments:
A Shimazdu UV-2450 PC series UV visible spectrophotometer was used for measuring the absorbances of the solutions. Sartorious balance model –TTA 225 D, ID no QCI 017 balance was used for weighing.

Chemicals and Reagents**:**
Keterolac Tromethamine is a gift sample obtained from Hetero Drugs Ltd., Hyderabad. Methanol and hydrochloric acid are of analytical grade supplied by Bharath Scientifics, Hyderabad.

Preparation of standard stock solution (100 µg/mL): 10 mg of Keterolac Tromethamine weighed accurately and transferred into 100 mL volumetric flask and 50 mL of solvent acidic methanol was added, sonicated to dissolve, filtered and made upto the mark by the solvent.

Preparation of standard solutions (10 µg/mL): 10 mL of the standard solution is pippetted out into 100 mL volumetric flask and acidic methanol solvent is added, sonicated to dissolve, filtered through fitter paper and made upto the mark by the solvent. This solution is used for the U.V Spectrophotometric determinations of Keterolac Tromethamine.

Preparation of sample solution:
20 Toradol tablets were grinded into powder and accurately weighed equivalent to 10 mg of Keterolac Tromethamine is transferred into 100 mL volumetric flask, 50 mL acidic methanol solvent is added, sonicated to dissolve for some time, filtered and made upto the mark. 10 mL of the above solution is diluted to 100 mL by the solvent and the resulting solution is used for the U.V. Spectrophotometric determinations.

Validation of the method**:**
The U.V. Spectrophotometric method developed is validated as per ICH guide lines for the linearity, accuracy, precision, ruggedness and repeatability. The optical characteristics of Keterolac Tromethamine are shown in Table 1.

Table.1: Optical characteristics of Keterolac

S. No.	Parameter	Values
1.	Absorbance maximum wave length (nm)	316
2.	Linearity range (Beer's Law Limits)	2.5 – 15.0 µg/mL
3.	Correlation coefficient	0.9999
4.	Regression equation	y=0.049x
5.	Slope	0.049
6.	Standard deviation (σ)	0.2677
7.	LOD $\left(\frac{3.3\sigma}{S}\right)$ µg/mL	15.33
8.	LOQ $\left(\frac{10\sigma}{S}\right)$ µg/mL	46.47

Linearity**:**

The linearity of the method (Beer's Law limits) is studied by taking the absorbance's of six solutions of different concentrations of Keterolac Tromethamine at 316 nm wave length and a calibration Curve was constructed which is shown in Fig.2.The amounts of Keterolac present in the linear solutions and their absorbances are shown in Table.2.

Conc(µg)	Absorbance
0.00	0.00
2.50	0.124
5.00	0.248
7.50	0.371
10.00	0.496
12.50	0.619
15.00	0.744

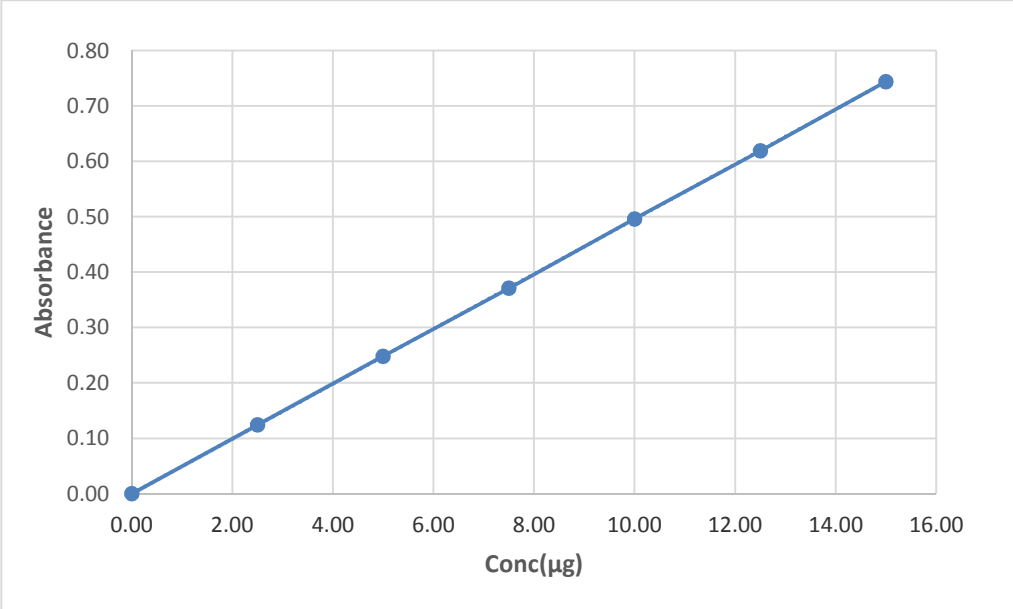

Fig.2 Linear Calibration curve of Keterolac Tromethamine

Table.2: The amounts Keterolac Tromethamine present and their absorbance's at 316 nm

S. No.	Level of the solution %	Amount of the Drug µg/mL	Absorbance
1	25	2.5	0.124
2	50	5.0	0.248
3	75	7.5	0.371
4	100	10.0	0.496
5	125	12.5	0.619
6	150	15.0	0.744

Accuracy (Recovery Studies):
The accuracy of the method is determined by the standard addition of API and recovery method. A known amount of pure Keterolac Tromethamine is added to the pre analysed sample of Keterolac Tromethamine(10 µg/mL) solution and the resulting solution is analysed by the present method and %RSD is calculated. The lower value of %RSD indicates the accuracy of the method. The amounts of Keterolac Tromethamine recovered – accuracy studies are shown in Table 3.

Table 3: Amounts of Keterolac recoved – Accuracy studies

S. No.	Level %	Amount taken µg/mL	Amount of API added µg/mL	Total amount present µg/mL	Amount recovered	% of recovery
1.	80	10	8	18	17.862	99.23
2.	100	10	10	20	19.863	99.315
3.	120	10	12	22	21.885	99.480

Precision:
The precision of the method is the concurrence among the individual results taken under identical conditions on different days and on the same day. By analysing 8 µg/mL ,10 µg/mL and 12 µg/mL of Keterolac Tromethamine three times in each day and one time each in a day in three days, precision of the method is determined. The results of precision are shown in Table 4.

Table.4: Results of Precision

S. No.	Level%	Conc. of solution µg/mL	Intraday % RSD	Interday %RSD
1	80	8	0.146	0.145
2	100	10	0.116	0.117
3	120	12	0.098	0.097

Ruggedness**:**
The ruggedness of an analytical method is determined by the analysis of the same sample under different conditions, such as by different analysts, different instruments in different laboratories etc. The ruggedness of the proposed method is determined by the analysis of identical solutions by different analysts under identical conditions. The results of ruggedness are shown in Table 5.

Table 5: Results of Ruggedness

S. No.	Amount taken	Analyst – I	%RSD	Analyst – II	% RSD
1	10 µg	9.818 µg	0.455	9.914 µg	0.407

Repeatability**:**
Six solutions of Keterolac Tromethamine are analysed and the repeatability is determined. The results of repeatability are shown in Table-6.

Table 6: Results of Repeatability

S. No.	Amount of the drug taken µg	Amount found µg	% Recovery	% RSD
1	10	9.92	99.2	0.084

Determination of Assay of the Sample**:**
Six identical solutions of the sample are taken and their absorbances are measured. By statistical methods, the %RSD value is evaluated .The results of pharmaceutical dosage form Toradol is shown in Table 7.

Tables 7: Results of Pharmaceutical Dosage form Toradol

S. No.	Amount of Toradol taken	Amount found	% of Assay
1	10 mg	9.93 mg	99.3

RESULTS AND DISCUSSION

The U.V. Spectra of Keterolac Tromethamine has shown maximum absorbance at 316 nm wave length. Keterolac Tromethamine obeys Beer's Law in the concentration range 2.5-15 µg/mL with correlation coefficient 0.9999 .The optical characteristics of Keterolac Tromethamine are show in Table 2. Sample is analysed by the present method and the % of amount found was 99.3 which is in the range 100±1. The accuracy of the method is tested by adding known amount of the Keterolac Tromethamine API to the pre- analysed sample and the amount of assay present in

the resulting solution is determined by the present method. The %RSD is less than 2 which indicates that the method is accurate. By using intraday and interday analysis of solutions under identical conditions, the precision is determined. By performing the analysis by different analysts ruggedness is obtained. The %RSD of Ruggedness is less than 2 and hence the method is rugged. Six solutions of Keterolac Tromethamine are analysed six times for studying the repeatability is determined. The present method can be applied for the determination of pharmaceutical dosage forms of Keterolac Tromethamine.

CONCLUSION

The present method is found to be simple, accurate, precise, economical and reproducible for the estimation of Keterolac Tromethamine in pharmaceutical dosage forms without interference of excipients present in the tablet formulation. Hence, it can be used for the routine analysis of Keterolac Tromethamine in pharmaceutical dosage forms in quality control laboratories.

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