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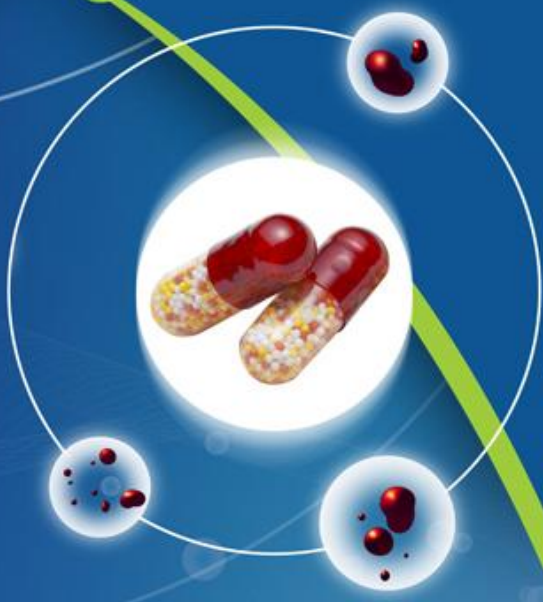

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Research Article

QUANTITATIVE DETERMINATION OF KETOROLAC TROMETHMINE FROM OPHTHALMIC EYE DROP FORMULATION BY UV-SPECTROPHOTOMETRY

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ABSTRACT:
A simple, accurate and economical UV-Spectrophotometric method has been developed for routine analysis of ketorolac tromethmine (KT) in ophthalmic solution. In saline phosphate buffer (PBS) pH 7.2 and simulated tear fluid (STF)/bicarbonate ringer solution pH 7.2, Ketorolac tromethmine showed maximum absorbance at 316.0 nm. In this method Ketorolac tromethmine obeyed linearity in the concentration range of 1 - 10 µg/mL (r^2 > 0.99). Proposed methods were applied for ophthalmic solution and amounts of ketorolac tromethmine estimated by this method were 99.91 ± 1, 99.46 ± 1 in phosphate buffer and in simulated tear fluid respectively. Methods were validated statistically.

KEYWORDS: *Ketorolac tromethmine; UVSpectrophotometry.*

INTRODUCTION:

Ketorolac is a non-steroidal anti-inflammatory drug (NSAID), which has potent analgesic and anti-inflammatory activity due to prostaglandin related inhibitory effect of drug. Ketorolac is available as a tromethamine salt, ketorolac tromethamine (KT), which is water-soluble. Aqueous ocular drops of KT (0.5%) are an effective anti-inflammatory agent for topical use following cataract surgery and intraocular lens implantation. KT is also a viable alternative to corticosteroids in treating ocular inflammation in the presence of pathogens. Ketorolac is applied topically in the management of seasonal allergic conjunctivitis, postoperative ocular pain and inflammation1-2.

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In literature survey analytical methods including RP-HPLC3-5 and UV-spectroscopic6-8 and HPTLC9-14 methods have been reported for the estimation of Ketorolac tromethmine in bulk, pharmaceutical formulation and in biological samples. In present study simple, economical, accurate reproducible analytical method with better detection range for estimation of Ketorolac tromethmine in ophthalmic solution were developed.

MATERIALS AND METHODS:

Chemicals

Ketorolac tromethmine was supplied as a gift sample by torrent Pharmaceuticals Ltd, Ahmadabad. Ophthalmic solution (eye drop Acular, Cipla) was procured from local market, containing Ketorolac tromethmine 5mg/mL.

Instrumentation

A UV-Visible spectrophotometer (1700 Shimadzu) with spectral bandwidth 1 nm was employed for all spectroscopic measurements.

Selection of common solvent

The solubility of Ketorolac tromethmine was tested in various buffers such as acetate buffer I.P. (pH 6.0 & 6.5), citrophosphate buffer B.P. (pH 6.0 and 6.2) phosphate buffer USP (pH 7.2 and 7.4) and water in order to select a suitable vehicle. Solutions of Ketorolac tromethmine in the above buffers were prepared to test its solubility at the dosage level desired (0.5% w/v). Phosphate buffer (PBS) pH 7.2 and bicarbonate ringer solution/simulated tear fluid (STF) (pH 7.2 were selected as common solvent for developing spectral characteristics of Ketorolac tromethmine. The selection was made after evaluating the solubility of Ketorolac tromethmine in different solvents.

Preparation of Stock standard solution and selection of wavelengths

A stock standard solution of Ketorolac tromethmine was prepared by dissolving 50 mg in 50 mL of Phosphate buffer pH 7.2 and simulated tear fluid pH 7.2 separately to get a concentration of 1mg/ml. 1 ml of this was further diluted to 100 ml with Phosphate buffer pH 7.2 and simulated tear fluid pH 7.2 separately to obtain concentrations 10 µg/mL. After proper dilutions, 10 µg/mL solution of KT was scanned in the UV-region i.e. 400 - 200 nm. Ketorolac tromethmine showed maximum absorbance at 316 nm.

Study of linearity curves

To examine the linearity of the assay, the calibration curve for of ketorolac tromethmine at a concentration range of 1-10 µg/mL in Phosphate buffer pH 7.2 and simulated tear fluid pH 7.2 was prepared in **figure 1& 2**. The optical characteristic and statistical data is shown in **Table 1**.

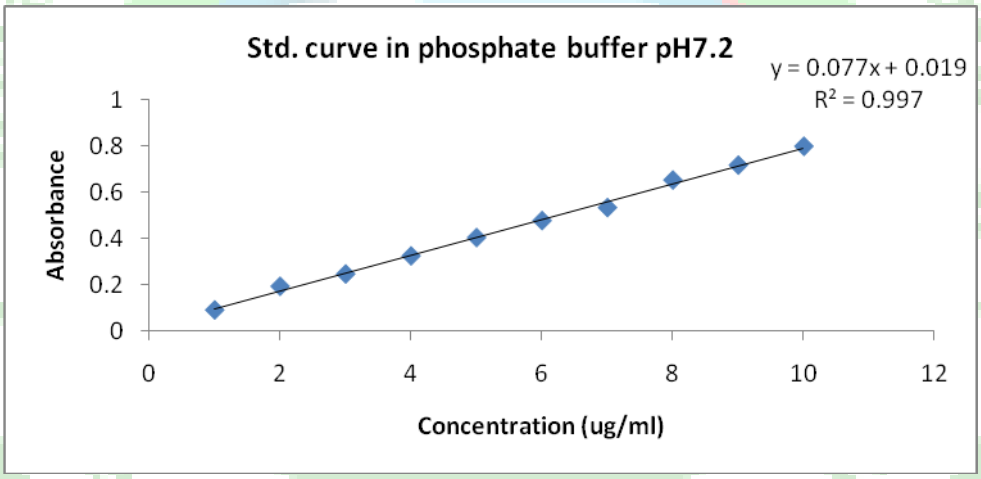

Fig 1: Standard calibration curve of Ketorolac tromethmine in PBS pH 7.2 at 316 nm

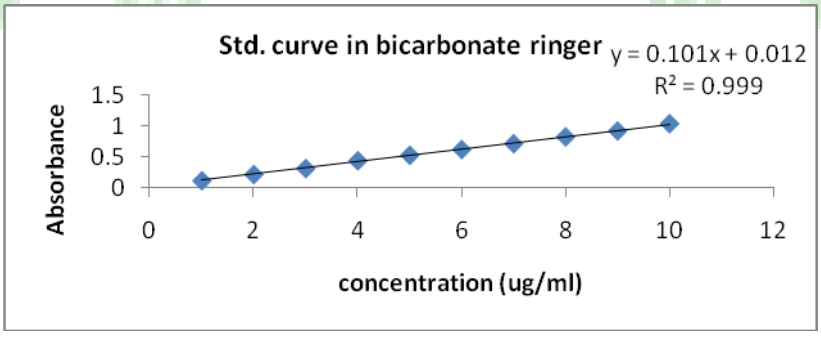

Fig 2: Standard calibration curve of Ketorolac tromethmine in STF pH 7.2 at 316 nm

Analysis of marketed ophthalmic eye drop formulation

An accurately measured volume of ophthalmic solution equivalent to 50 mg of ketorolac tromethmine was transfer into each 50 mL volumetric flask and volume was made up to the mark with Phosphate buffer pH 7.2 and simulated tear fluid pH 7.2, filtered through 0.45 µm Whatmann filter paper no.41. A suitable volume of

solution was further diluted with Phosphate buffer pH 7.2 and simulated tear fluid pH 7.2 to obtain concentration of 10 µg/mL of ketorolac tromethmine. The amounts were determined using respective linear regression equations. The analysis procedure was repeated for six times with ophthalmic solution.

RESULTS AND DISCUSSION:

In Phosphate buffer pH 7.2 and simulated tear fluid pH 7.2, Ketorolac tromethmine from ophthalmic eye drop formulation showed maximum absorbance at 316nm. In this method Ketorolac tromethmine followed linearity in the concentration range of 1 - 10 µg/mL. The amounts of Ketorolac tromethmine in ophthalmic solution were found to be 99.91 ± 1, 99.46 ± 1 in Phosphate buffer pH 7.2 *and* simulated tear fluid pH 7.2 respectively. Results acquired indicate that there was no interference from the excipients commonly present in marketed ophthalmic solution (Acular). Methods were validated for accuracy. The results from the validation of methods are given in **table 1.**

Table 1: Results of optical characteristics and validation of Ketorolac tromethmine by proposed methods

Parameter	In Phosphate buffer pH 7.2	In simulated tear fluid pH 7.2
Linearity range [µg]	1-10	1-10
Linearity equation	Y = 0.077x + 0.019	Y= 0.101 X + 0.012
Coefficient Correlation [r^2]	0.997	0.999
Drug content	99.91 ± 1	99.46 ± 1

CONCLUSION:

This developed method is simple, economical, accurate and precise and can be used for routine estimation of Ketorolac tromethmine from its pharmaceutical formulation.

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