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DETERMINATION OF DEXIBUPROFEN AND TRAMADOL HCl BY SIMULTANEOUS UV SPECTROSCOPIC METHOD FROM BULK AND PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

Development and validation of accurate, easy, error-free, specific and sensitive simultaneous UV spectroscopic method for determination of Dexibuprofen and Tramadol HCl in bulk as well as in pharmaceutical dosage form containing a blend of these two drugs. Method A i.e. simultaneous equation method and method B Area under the curve are applied for the estimation of DEX and TRAM. Systematic analytical methods are employed in line using 264 nm and 271 nm i.e. λmax of DEX and TRAM taking ethanol as a solvent. DEX and TRAM separately and in a blend of mixture comply with beer's law in concentration range 100-500µg/ml and 20-120µg/ml. In addition, proposed study concludes that two drugs do not interact with each other in a solution. Both the drugs are found to be accurate and reproducible for the desired linearity concentration range. This method can be applied effectively in the regular simultaneous assessment of both the drugs from the dosage form free of interference due to excipients.

Keywords: Exibuprofen, Tramadol, Simultaneous and UV method.

INTRODUCTION

Dexibuprofen is chemically (S)-Alpha-Methyl-4- (2-Methyl Propyl) Benzene Acetic Acid. Dexibuprofen is a pharmacologically active enantiomer of racemic ibuprofen. Racemic ibuprofen is a non-steroidal substance with anti-inflammatory and analgesic effects. Its mechanism of action is due to the inhibition of prostaglandin synthesis[1].Tramadol Hcl is chemically rac-(1R,2R)-2-(dimethylaminomethyl)- 1-(3-methoxyphenyl)-cyclohexanol it work through modulation of the GABAergic, noradrenergic and serotonergic systems, in addition to its mild agonism of the µ-opioid receptor[2].It is reported that the addition of Tramadol HCl to existing NSAID therapy provides effective pain relief in patients with osteoarthritis flare pain. Tablets containing 400mg of Dexibuprofen and 50mg of Tramadol HCl combination if taken twice in a day are effective novel dosage forms for osteoarthritis.

MATERIALS AND METHODS

MATERIALS

Shashun pharma and Organosys pharma provided a gift sample of Dexibuprofen and Tramadol HCl respectively.Ethanol AR grade procured from Vivochem B.V.

Equipment

UV spectra of reference standard as well as sample solutions and absorbance of all the sample solutionswere recorded using a UV spectrophotometer system (Jasco V-530).Mettler Toledo balances are used for weighing all samples.

Procedure

Selection of solvent and wavelength

Solubility of Dexibuprofen and Tramadol HCl was scanned invarious solvents like ethanol, methanol, and water. All drug solutions were examined for UV spectra. An ethanolic solution of both the drugs has shown maximum absorbance compared to other solvents. Two wavelengths i.e. 264 nm and 271 nm selected as λmax of Dexibuprofen and Tramadol HCl.

Drug solutions
Accurately weighed 50 mg of standard DEX and TRAM solubilized in 20 ml ethanol and volume was made up to 50 ml using ethanol as a solvent in 50 ml volumetric flask. The drug solution was filtered through a 0.45µ filter.

Preparation of calibration curve
Aliquots of standard drug solutions were withdrawn i.e. 1-6ml for DEX and 0.2-1.2 ml for TRAM and volume was made up to 10 ml using ethanol as solvent. Concentration versus absorbance was plotted and recorded to be linear for both the drugs as shown in Fig no 5 and 6.The calibration curve was plotted at a concentration range from 100 -500 µg/ml and 20- 120 µg/ml for Dexibuprofen and Tramadol HCl respectively. The correlation coefficient was found to be 0.9983 and 0.9982 respectively for Dexibuprofen and Tramadol as shown in fig 4 and 5.

Precision
Suitable statistical estimation done to confirm the reproducibility of the developed method.The amount of drugs were determined thrice in a day at an interval of 2 hours on three different days for inter and intraday study respectively.

Limit of detection (LOD)
Minimum concentration of drug solution under study which can be detectable but not measurable is LOD. It is recorded as 1µg/mL and 0.5µg/mL for DEX and TRAM respectively.

Limit of quantification (LOQ)
It is a minimum drug solution under study which can be detectable as well as measurable is LOQ. It is recorded as 10 µg/mL and 5 µg/mL for DEX and TRAM respectively.

Percentage recovery studies
Precision of the developed method was estimated in terms of percentage recovery studies. The Amount of drug added to the solvent and amount of drug recovered after taking absorbance of drug solution at their λmax were evaluated. The procedure was repeated for three times and the concentration of drug in solution was recorded as a percentage of the analyte.

Spectroscopic simultaneous equation method (Method A)

For computable estimation of both the drugs understudy based onUV spectra of each drug two wavelengths i.e. λmax of each drug is selected. Two wavelengths i.e. 264 nm λmax of Dexibuprofen and 271 nm λmax of Tramadol HCl were fixed for the systematic analytical method development. Sets of the simultaneous equation were developed taking the absorptivity coefficient at selected wavelengths in an account. To estimate the amount of each drug in mixturetwo sets of the simultaneous equation were constructed.
The amount of each drug from the blend was computed using the following two sets of simultaneous equations

$$CDEX = A2 \times at1 - A1 \times at2 / ad2 \times ad1 - at1 \times ad2 \ldots\ldots (1)$$

$$CTRAM = A1 \times ad2 - A2 \times ad1 / ad2 \times at1 - at1 \times ad2 \ldots\ldots (2)$$

Where ad1, ad2, at1, at2 are absorptivities of DEX and TRAM at 264 and 271nm respectively. The absorbance of diluted mixed standards at 264 and 271 nm are denoted by A1 and A2. CDEX, CTRAM representsthe concentration of respective drugs.

The area under curve (Method B)
Additional other procedure designed for determination of two drugs in a blend using calculation of area under the curve of the spectra at a range of 259- 266nm and 267-275nm. Two sets of equations designed by evaluating the absorptivity coefficient of both the drugs at each finalized wavelength scale.

$$AUC1 = 0.8971CDEX + 0.2429CTRAM \ldots\ldots (III) (\lambda 259\text{-}266nm)$$

$$AUC2 = 4.341CDEX + 2.6238CTRAM \ldots\ldots (IV) (\lambda 267\text{-}275nm)$$

Where AUC1 and AUC2 are the area of under the curve of drug solutions when scanned at wavelength range 259-266nm and 267-275nm respectively. CDEX and CTRAM are concentrations ofDEXand TRAM respectively. The amount of each drugfrom admixture computed using mathematical expressions (III), (IV).

Assay of dosage form
Tablet
Meticulously weighed powder of ten tablets equivalent to 400mg of DEX and 50mg TRAM was weighed. The weighed powder was solubilized in ethanol and volume was made up to 100 ml using ethanol as a solvent. The drug solution was sonicated for 15-20 mins

and filtered through 0.45µ filter paper.Aliquots of drug solutions were diluted with ethanol to obtain 200 µg/mL and 25 µg/mL of DEX and TRAM respectively. Prepared sample solutions assessed by present proposed method.Results shown in table 3.

Capsule

Liquid from all ten capsules were emptied in a test tube. The volume of liquid equivalent to 400 mg of DEX and 50 mg of TRAM was solubilized in ethanol and volume was made up to 100 ml using ethanol as a solvent. The drug solution was sonicated for 15-20 mins and filtered through 0.45µ filter paper. Aliquots of drug solutions were diluted with ethanol to obtain 200 µg/ml and 25 µg/ml of DEX and TRAM respectively. Prepared sample solutions assessed by present proposed method.Results shown in table 3.

RESULT AND DISCUSSION

It is reported that synergism exists between Tramadol and Dexibuprofen but the simultaneous UV spectroscopic method for measurement of each drugfrom mixture doesn't exist.So,the above designed analytical procedures for determination of Dexibuprofen and Tramadol HCl in intermixed dosage form were found to be specific, peculiar,easy,reproducible, quick and profitable. The linearity range of the developed method was recorded in the concentration range 100- 500 µg/ml and 20-120 µg/ml for Dexibuprofen and Tramadol HCl. All statistical parameters of the developed method were validated according to ICH guidelines. The level of accuracy for the proposed method was estimated at 60, 80, and 100,120%. The percentage of recovery for all developed methodsis between 99 to 100%. Interdayand intraday variation for both the drugs was found to be at a minimum level. These methods can efficaciously pre-owned for determining Dexibuprofen and Tramadol HCl simultaneously in amalgamate bulk as well as the dosage form.

CONCLUSION

The proposed UV spectroscopic method is simple, precise, easy and also repeatable for evaluation of Dexibuprofen and Tramadol HCl simultaneously from the bulk and pharmaceutical dosage form.

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Table 1: Statistical Parameter

Parameter	DEX	TRAM
Linearity range	100µg/ml - 500µg/ml	20µg/ml -120 µg/ml
Slope value	0.0088	0.00044
Intercept	0.0013	0.0053
Correlation coefficient	0.9983	0.9982
Limit of detection	1µg/ml	0.5 µg/ml
Limit of quantification	10 µg/ml	5 µg/ml
InterdayPrecesion (%RSD)	0.31	0.0732
Intraday Precision(%RSD)	0.63	0.503
Robustess (%RSD)	0.402	0.25

Table 2: Results dosage formulation

Type of Method	Type Dosage form	mg/dosage form	Obtained /dosage form (mg)	Percentage recovery ± SD*
Method A	Tablet	400mg 50mg	399.3mg 49.8mg	99.82±0.43 99.6±0.21
Method B	Tablet	400mg 50mg	399.7mg 49.6mg	99.92 ±0.23 99.2±0.11
Method A	Liquid filled Capsule	400mg 50mg	400.01mg 49.9mg	100.02 ±0.12 99.8±0.32
Method B	Liquid filled Capsule	400mg 50mg	399.9mg 49.9mg	99.97±0.1 99.8±0.33

*average of 6 tablets/capsules

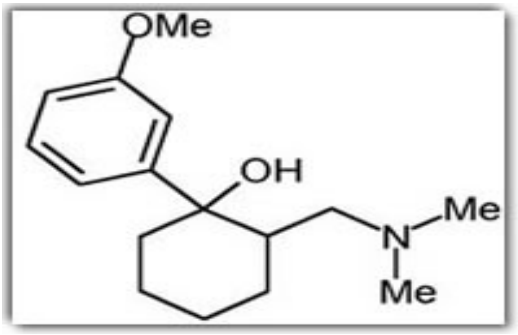


Fig. 1: Dexibuprofen

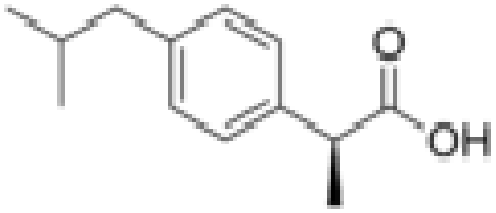


Fig. 2: Tramadol

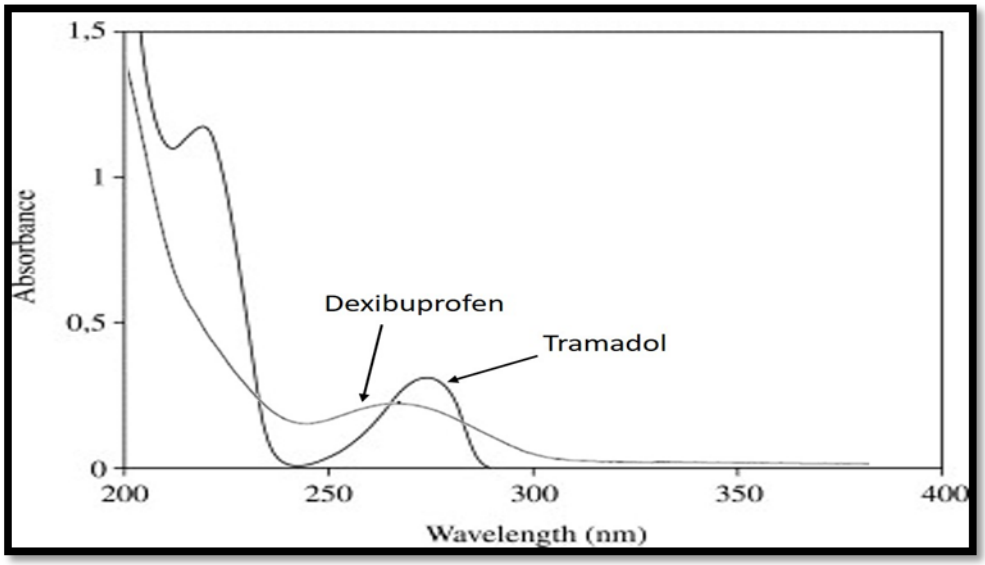
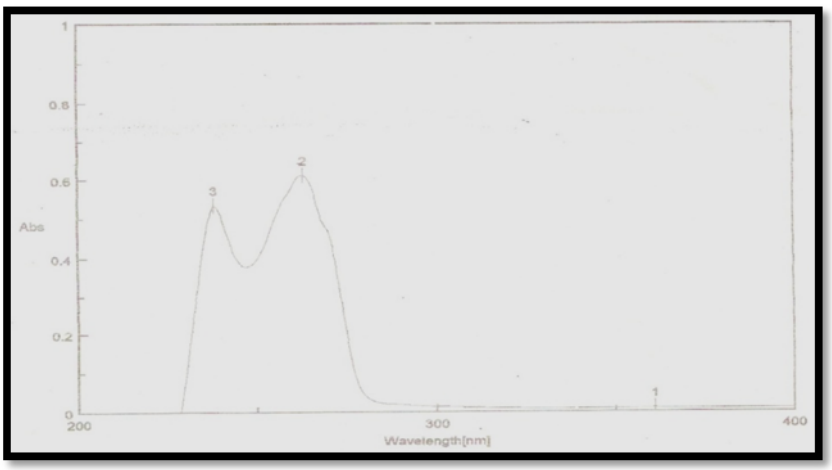
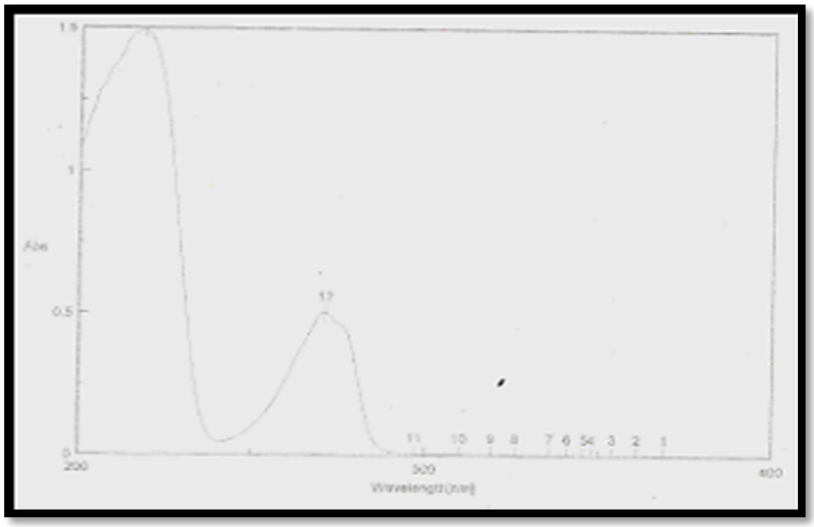


Fig. 3: Overlay spectra of Dexibuprofen and Tramadol HCl



DEX



TRAM

Fig. 4: UV spectrum of Dexibuprofen and Tramadol

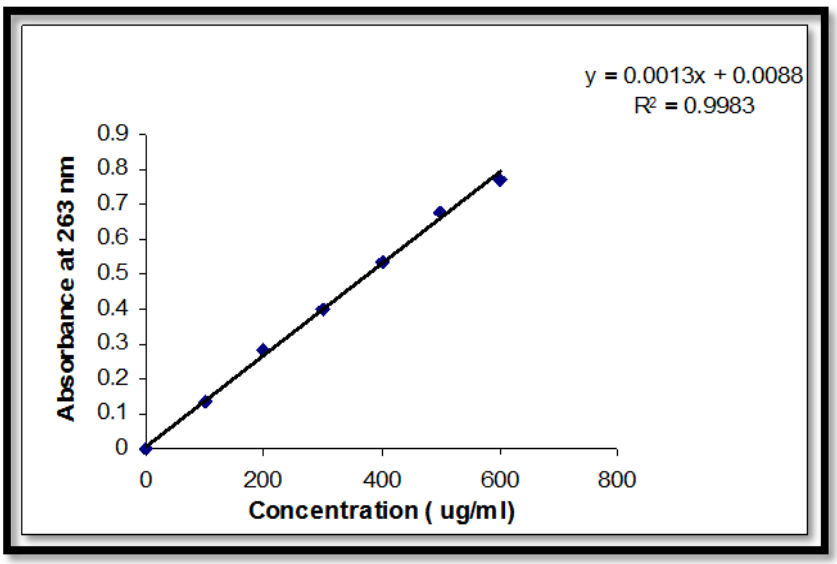


Fig. 5: Calibration curve of Dexibuprofen

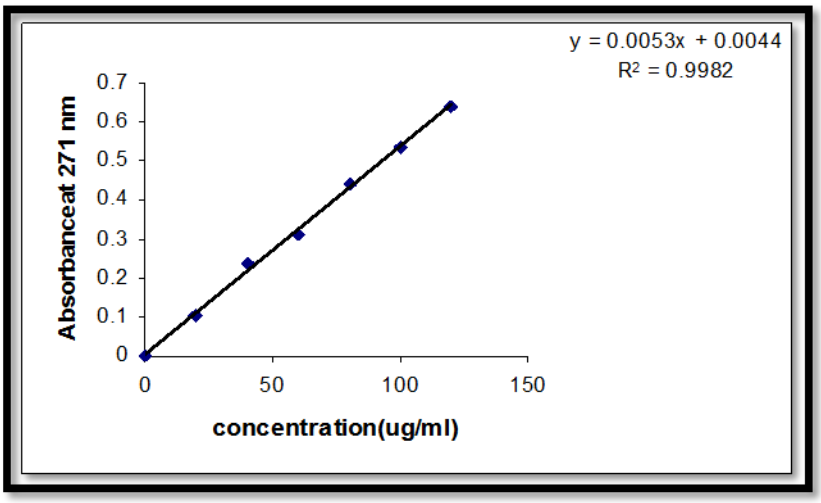


Fig. 6: Calibration curve of Tramadol HCl

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