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Research Article

UV Spectrophotometric Method Development and Validation for Quantitative Estimation of Diclofenac Sodium

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ABSTRACT

Aim: UV Spectrophotometric Method Development and Validation for quantitative estimation of Diclofenac Sodium. **Objective:** U.V Spectrophotometric method have been widely employed for determination of analyte in a mixture. Our aim is to develop spectroscopic method for estimation of the diclofenac sodium in ternary mixture by using U.V spectrophotometry. **Methodology:** The method was validated as per ICH guidelines. The recovery studies confirmed the accuracy and precision of the method. **Conclusion:** It was successfully applied for the analysis of the drug in bulk and could be effectively used for the routine analysis. **Key words:** Diclofenac sodium, UV spectrophotometric method, Validation.

Introduction

Diclofenac sodium belong to the family of non-steroidal anti-inflammatory drugs (NSAID) or cyclo-oxygenase (COX) inhibitors. It is an effective anti-inflammatory, analgesic and antipyretic agent. It is commonly used in the treatment of acute and chronic pain, rheumatoid and osteoarthritis. Chemically it is 2-(2, 6-dichlorophenyl) amino benzeneacetic acid 4-(3H 1, 2, dithiol-3-thione-5-yl) phenyl ester and is a low-molecular-weight drug (MWt: 318.13). The present work describes the development of a simple, precise, accurate and reproducible spectrophotometric method for the estimation of Diclofenac sodium in pharmaceutical dosage forms. The developed method was validated in accordance with ICH Guidelines and successfully employed for the assay Pharmaceutical preparation and dosage form (Kashiwame et al., 2011; Dangre et al., 2015; Sawale et al., 2015).

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Material and Method

Material

Diclofenac sodium supplied as a gift sample by Loba chem. Pvt. Ltd (Mumbai, India) used as working standard.

Instrumentation

A double beam UV-VIS spectrophotometer (UV-1700, Shimadzu, Japan) connected to a computer loaded with spectra manager software UV Probe was used. The spectra were obtained with the instrumental parameters as follows: Wavelength range: 200–800 nm. All weights were taken on an electronic balance (Model Shimadzu AUX 120).

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Preparation of standard stock solution

According to European pharmacopoeia, 10 mg of Diclofenac sodium was dissolve in 100 ml of methanol (100 µg/mL). Out of this stock 0.2-1.2 ml was pipetted and diluted up to 10 ml by methanol (2-12 µg/mL) and examined between 200-400 nm. The maximum absorbance was determined using UV-Vis Specrophotometer (UV-1700, Shimadzu, Japan) to confirm the λmax of the drugs.

Validation of analytical method

The analytical performance characteristics which may be tested during methods validation: % Recovery, Precision, Ruggedness and sensitivity (Han et al., 2003; Sharma et al., 2005; Aggarwal et al., 2006).

Results and Discussion

Method Development

The solution of diclofenac sodium in methanol was found to exhibit maximum absorption at 276 nm after scanning on the UV-Vis spectrophotometer which was reported as λmax in the literature and the procured drug sample of diclofenac sodium complies with the reference spectra (Figure 1).

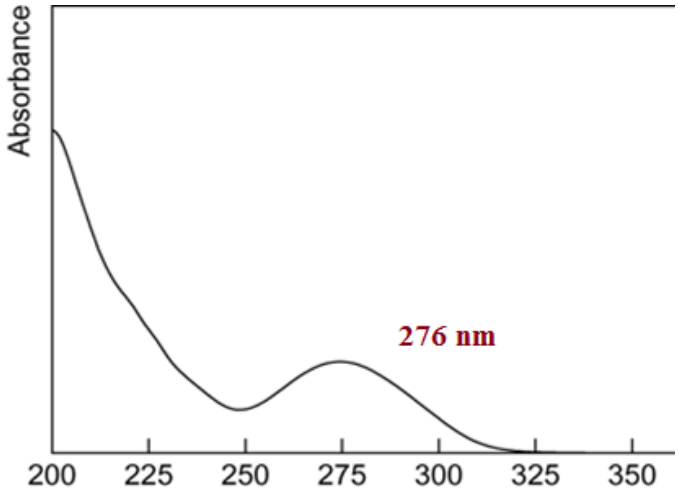

Figure 1. UV spectra of Diclofenac sodium

Linearity study

Accurately weighted diclofenac sodium (10 mg) was dissolved in 100 ml of methanol to obtain working standard of 100 µg/ml. Aliquots were pipetted from the stock solution of drug and were transferred to 10 ml volumetric flask, the final volume was adjusted with methanol so that concentration of 2-12 µg/ml could be made. Absorbance of the above solution were taken at 276 nm by using UV-Vis spectrophotometer (UV-1700, Shimadzu, Japan) against the blank solution prepared in the same manner without adding the drug. A graph of absorbance vs concentration was plotted (Figure 2) and R^2 was found to be 0.9986.

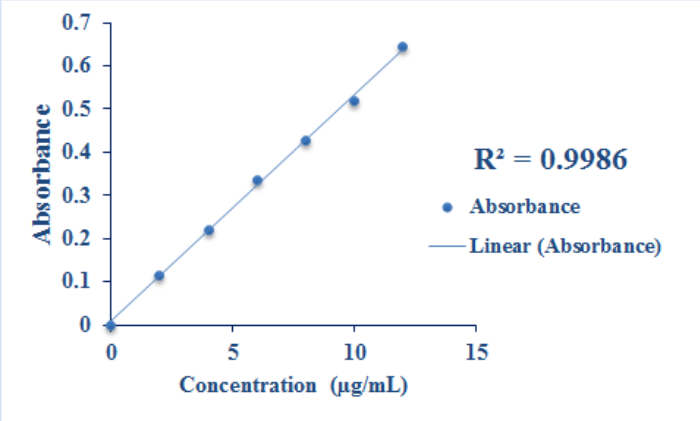

Figure 2. Calibration curve of Diclofenac sodium

Validation of analytical method

Recovery

Recovery study is performed by standard addition method by adding the known amount of diclofenac sodium (Working standard) at two different concentration levels i.e 80%, 100% of assay concentration and % recovery for all these drug were calculated. Result was reported in Table 1.

Table 1. Recovery study

Drug	Initial amount (µg/ml)	Added Amount (µg/ml)	% Recovery	% RSD (n = 3)
Diclofenac sodium	2	1.9	100.15	0.07
	2	1.8	100.98	0.05

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Precision

Intra-day precision was determined by analysing, the two different concentrations 2 mg/ml, 3 mg/ml containing diclofenac sodium, for three times in the same day (n = 3) Table 2. Inter-day variability was assessed using above mentioned three concentrations analysed on three different days, over a period of one week (n = 3) Table 2.

Table 2. Presion study

		Intra - Day		Inter - Day	
Drug	**Con. (µg/ml)**	**Mean ± SD**	**% RSD**	**Mean ± SD**	**% RSD**
Diclofenac sodium	2	2.0 ± 0.0016	0.01	1.9 ± 0.0014	0.07
	3	2.9 ± 0.0014	0.05	2.9 ± 0.0048	0.06

Ruggedness

From stock solution, sample solution containing diclofenac sodium (2 µg/ml) was prepared and analyzed by two different analysts using similar operational and environmental conditions (Table 3) (n = 3).

Table 3. Ruggedness study

	% Amount Found		% RSD	
Drug	**Analyst I**	**Analyst II**	**Analyst I**	**Analyst II**
Diclofenac sodium	100.44	99.44	0.01	0.05

Sensitivity

Sensitivity of the proposed method was estimated in terms of Limit of Detection (LOD) and Limit of Quantitation (LOQ) (Table 4).

Table 4. Sensitivity study

Drug	LOD	LOQ
Diclofenac sodium	0.19 ± 0.004	0.44 ± 0.011

Conclusion

The proposed UV spectrophotometric method was found very simple, rapid and economical. The method is validated in compliance with ICH guidelines is suitable for estimation of diclofenac sodium with excellent recovery, precision and linearity.

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