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COLORIMETRIC DETERMINATION OF DICLOFENAC POTASSIUM IN TABLET DOSAGE FORM USING BROMOCRESOL GREEN AS A CHROMOGENIC REAGENT

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ABSTRACT

Objective: The primary goal of this study is to use the colorimetric approach to estimate the dosage of Diclofenac potassium in tablet dosage form. The developed approach has been validated in accordance with ICH Q2(R2) requirements. **Methods and materials:** Chromatographic quantification was performed with a detection wavelength of 540 nm and a concentration range of 5-25 µg/ml. Diclofenac potassium was shown to have a correlation coefficient of 0.992. **Result:** Diclofenac potassium's regression equation was determined to be y = 0.030x + 0.385. Diclofenac potassium's detection limit (DL) and quantitation limit (QL) were determined to be 0.544 µg mL-1 and 1.650 µg mL-1, respectively. In accordance with ICH Q2(R2) criteria, the developed method was validated. For both the system and intermediate precision, the percentage RSD was under 2%. Diclofenac potassium recovery was found to be over 99%. **Conclusion:** The results show that the developed method is simple, reliable and cost-effective, making it suitable for quality control of Diclofenac potassium in tablets.

KEYWORDS: Diclofenac potassium, Colorimetric, Validation, Stability, ICH.

INTRODUCTION

Diclofenac is offered in two enteral formulations, Diclofenac sodium and Diclofenac potassium. Chemically, diclofenac potassium (DCL) is [2-[(2,6-Dichlorophenyl) Amino]Phenyl] Acetate. Different pharmacopoeias have published dosage formulations of diclofenac potassium.[1-3] Diclofenac potassium inhibits both leukocyte migration and the enzyme cyclooxygenase (COX-1 and COX-2), which results in the peripheral suppression of prostaglandin formation. Diclofenac potassium is designed to be absorbed and released in the stomach.[4–7]

Diclofenac potassium and its combinations in pharmaceuticals or biological fluids have been analyzed using a variety of techniques, including spectroscopy[8–15], HPLC[16–25], Bioanalytical[26], UPLC[27], and HPTLC.[28] Diclofenac potassium in tablet dose form cannot be estimated using any colorimetric approach. Therefore, it was believed that an analytical method for estimating Diclofenac potassium needed to be developed.

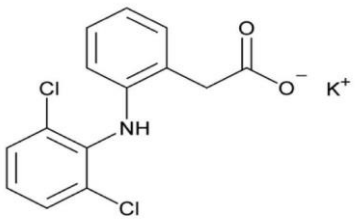

Figure 1: Chemical structure of Diclofenac potassium.

Diclofenac potassium has been determined in pharmaceutical formulations using a variety of techniques, but each of these techniques necessitates the use of costly reagents that are not easily accessible or sophisticated equipment (like HPLC) that is costly and requires an expert to operate in addition to being difficult to maintain in developing and academic laboratories.

The goal of the current study is to provide a colorimetric method that is easy to use, sensitive, accurate, affordable, and verified in accordance with ICH recommendations for determining the amount of diclofenac potassium in tablet dosage form.[29-30]

MATERIALS AND METHODS

Reagents and Chemicals

Each reagent used in the present research was of analytical quality. We purchased sodium hydroxide and methanol from Finar Chemical Ltd. We purchased sodium nitrite and bromocresol green from Ranbaxy Chemicals in New Delhi. 100 mg Diclofenc potassium tablets (Voveflam), made by Care Formulations Labs, were bought from a nearby pharmacy.

Instruments and apparatus

Shimadzu's digital balance was used to measure drug samples during the study. Eastimation was done using a Suntech colorimeter.

Preparation of standard solutions

Diclofenac Potassium standard stock solution: (1000 µg/mL)

Diclofenac potassium (10 mg) was weighed and transfer into a 10 ml volumetric flask. Methanol was used to bring the volume up to mark.

Diclofenac Potassium working standard solution: (100 µg/mL)

Transfer 1 mL of the Diclofenac Potassium stock solution to a 10 ml volumetric flask, then add methanol to get the volume up to mark level.

Preparation of 0.1 N NaOH

A 0.1 N solution of sodium hydroxide was prepared by dissolving 1.0 g of pellets in 100 ml of distilled water and further made up to a volume (250 mL) with more distilled water.

Preparation of 1% w/v $NaNO_2$

Weigh accurately 1 g of $NaNO_2$ in 100 ml volumetric flask and dilute to a final volume of 100 ml with distilled water.

Selection of Detection Wavelength

One ml of the standard stock solution and one ml of the bromocresol green solution were put to a test tube. For twenty minutes, the mixture was left to stand. Than, add one ml of 0.1 N NaOH solution and one ml of 1% w/v $NaNO_2$ solution. After a baseline correction using the blank solution (1 ml of Bromocresol green + 1 ml of $NaNO_2$ solution + 1 ml of 0.1 N NaOH solution), the resulting bluish green solution was scanned between 200 and 800 nm to determine the wavelength of maximum absorption (λmax).

Validation of developed chromatographic method

Colorimteric method for analysis of Diclofenac sodium was validated as per ICH guidelines.[29-30]

a) Linearity and Range

The linearity for Diclofenac Potassium was assessed by analysis of standard solutions in range of 5-25 µg/ml. 0.5, 1.0, 1.5, 2.0 & 2.5 ml solutions were pipette out from the working standard solution of Diclofenac Potassium (100 µg/ml) and transfer to 10 ml volumetric flask, 1 ml of Bromocresol green solution was added. The mixture was allow to stand for 20 minutes. Than, add 1 ml of 1% w/v of $NaNO_2$ solution and 1 ml of 0.1 N NaOH solution, then make up with methanol to obtain 5, 10, 15, 20, 25 µg/ml for Diclofenac Potassium. Measure the absorbance of all solutions at 540 nm.

b) System precision

Repeatability

Diclofenac Potassium (15 µg/mL) in a standard solution was examined six times, absorbance was measured, and the % R.S.D. was calculated.

c) Intermediate precision

The intermediate precision of the analytical procedure was shown to be intraday and interday precision. After analyzing a standard solution containing Diclofenac Potassium (10, 15, and 20 µg/ml) on the same day (Intraday Precision) and three separate days (Interday Precision), the average Absorbance and % R.S.D. were calculated.

d) Accuracy (Recover study)

Diclofenac Potassium (10 µg/ml) solution was spiked with 80%, 100%, and 120% of standard solution in three separate flasks labeled A, B, and C. At 540 nm, the absorbance was measured. Each level's Diclofenac potassium was determined, along with the percentage of recoveries.

e) Limit of Detection (LOD) and Limit of Quantitation (LOQ)

Based on standard deviation of y-intercepts and mean slop of calibration curves, LOD and LOQ were calculated as per ICH guidelines.

f) Robustness

The robustness of method was determined by deliberated change in wavelength (± 30 nm). The effect on Absorbance was calculated as % RSD.

Assay of Tablets

Twenty tablets was weighted and equivalent to 10 mg Diclofenac Potassium was taken and transferred to 10 ml volumetric flask and 6 ml of methanol was added and the

solution was shaked for 15 minutes and sonicated for 30 min in sonicator and volume was made up with methanol, 0.1 ml from this solution was taken and transferred to 10 ml volumetric flask and volume was made with mobile phase to prepare working solution 10 µg/ml for Diclofenac potassium. The developed spectrometric method was used to estimate Diclofenac potassium in tablets.

RESULTS AND DISCUSSION

Method development

In current research work, maximum wavelength selected for detection is 540 nm which is used for further detection.

Method Validation

Linearity and Range

Figure 2 and Table 1 illustrate the linear calibration curve for Diclofenac potassium over the concentration range of 5-25 µg/ml. The calibration curve's regression equation, y = 0.030x + 0.385, was found to have a 0.992 correlation coefficient (R^2).

Table 1: Linearity data of Diclofenac potassium (5-25 µg/ml).

Concentration (µg/ml)	Absorbance (Mean ± SD) (n=6)
5	0.550 ± 0.010
10	0.700 ± 0.013
15	0.833 ± 0.007
20	0.978 ± 0.006
25	1.184 ± 0.005

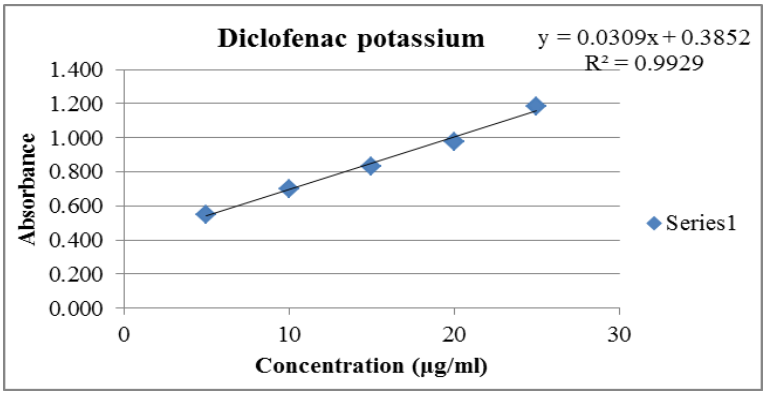

Figure 2: Calibration Curve of Diclofenac Potassium.

System Precision (Repeatability)

Six replicates of the Diclofenac potassium standard solution with concentrations of 15 µg/ml were used to evaluate repeatability. The % RSD was then determined to be 0.641 (Table 2).

Intermediate Precision

Table 2 also showed the results of Intraday and Interday Precision, which demonstrated intermediate precision. The developed approach was found to be exact when the % RSD was less than 2.

Table 2: Precision data for Diclofenac potassium.

Repeatability			
Conc. (µg/ml)	**Absorbance**	**Mean (n= 6) ± SD**	**% RSD**
15	0.835	0.832 ± 0.005	0.641
	0.837		
	0.829		
	0.838		
	0.824		
	0.834		
Intraday and Interday			
Conc. (µg/ml)	**Absorbance (Mean, n= 3) ± SD, % RSD**	**Absorbance (Mean, n= 3) ± SD, % RSD**	
10	0.720 ± 0.012, 1.733	0.722 ± 0.014, 1.874	
15	0.836 ± 0.010, 1.161	0.836 ± 0.015, 1.795	
20	0.973 ± 0.010, 1.013	0.974 ± 0.012, 1.245	

Accuracy (Standard addition method)
Diclofenac potassium samples (10 µg/ml) that had been previously tested and spiked with 80%, 100%, and 120% Diclofenac potassium standard were used for recovery testing. It was found that the recovery % was adequate (Table 3).

Table 3: Accuracy data for Diclofenac potassium.

Conc. level	Amt. taken (µg/ml)	Amt. added (µg/ml)	Amt. recovered (µg/ml)	% mean recovery	% RSD
80 %	10	8	8.015	100.18	0.82
100 %	10	10	10.055	100.55	0.69
120 %	10	12	12.031	100.26	1.49

LOD and LOQ
Diclofenac potassium's LOD and LOQ were found to be 0.544 µg/ml and 1.650 µg/ml, respectively, based on the standard deviation of slope and intercept.

Robustness
The robustness of the procedure was assessed using a solution containing 15 µg/ml of diclofenac potassium. The % RSD for absorbance was less than 2, as shown in Table 4.

Table 4: Robustness data for Diclofenac potassium.

Method Parameters	Optimized conditions	Deliberate changes	%RSD
Wavelength	540 nm	510	0.389
		570	0.826

Assay
Diclofenac potassium's mean (n=5) mg determined by the assay was 99.76 mg. Diclofenac potassium tablet assay results were 99.78% ± 0.297.

CONCLUSION
The spectroscopic method was successfully developed. The colorimetric method was successfully validated as per ICH guidelines. All validation parameters were found within the acceptance criteria. As per results, the validated method is novel, sensitive, linear, accurate, precise and robust for the analysis of Dasatinib in marketed tablet dosage form. It can be used for routine analysis of Dasatinib.

CONFLICT OF INTEREST
The authors declare no conflict of interest in this research.

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