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Original Article

UV spectrophotometric assay of Diclofenac sodium available brands

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Abstract

Diclofenac is a nonsteroidal anti-inflammatory drug (NSAID). A efficient, simple and least time consuming spectrophotometric method for the assay of diclofenac sodium has been developed. Comparison of assay of four different brands of diclofenac sodium (Dicloran, Defnac, Artifin, voltral) has also been done available in public medical store of Karachi, Pakistan. The assay is based on the ultraviolet UV absorbance maxima at about 276nm wavelength of diclofenac sodium using water as solvent. A sample of drug was dissolved in water to produce a solution containing diclofenac sodium. Similarly, a sample of ground tablets of different brand were dissolved in water and various dilutions were made. The absorbance of sample preparation was measured at 276nm against the solvent blank and the assay was determined by comparing with the absorbance of available brand. The method can be applied for the routine QC quantitation of diclofenac sodium in tablet formulation and active. Our results reveals that among all the four brands of diclofenac sodium (Dicloran, Defnac, Artifin, voltral) Defnac and voltral shows highest percentage assay 104% and Dicloran shows lowest value for percentage assay 96.4% , while artifin shows a percentage assay of 98.6%.

Key words : Diclofenac, percentage assay , UV spectrophotometer, ANOVA

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1. Introduction

Diclofenac 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. It acts by inhibiting COX activity and consequently the formation of pro-inflammatory mediators such as prostaglandins (PGs) and thromboxanes[1]. The mode of analgesic action of diclofenac sodium is through inhibition (COX-2) causing a reduction in the conversion of arachidonic acid into inflammatory prostaglandins[2]. Chemically it is 2-(2,6- dichlorophenyl) amino benzeneacetic acid 4-(3H-1,2,dithiol-3-thione-5-yl)phenyl ester [3] and is a low-molecular-weight drug (MWt:

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318.13)[4]. Diclofenac sodium was found to be the most commonly used off-label medicines in UK paediatric surgical wards [5,6] and exhibit anticancer effects [7] .Our research group has developed different assay methods which are very useful for different formulations[8-18].

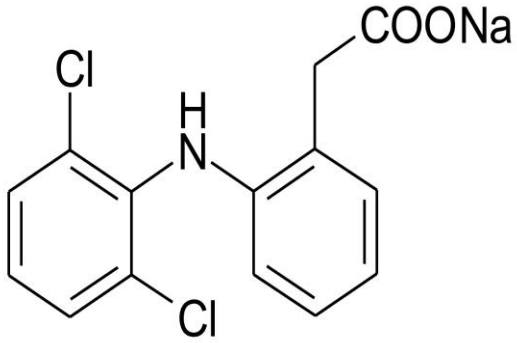


Figure 1: Structure of Diclofenac Sodium

2. Experimental Design

UV visible 1601 Shimadzu double beam spectrophotometer was used to measure of spectra. The solvent which was used for the assay was water.

Wavelength Selection

About 100 ppm of diclofenac sodium solution was accurately prepared in water. This solutions was scanned in the 200-400 nm UV region. The wavelength maxima (λmax) was observed at 340 nm and this wavelength was adopted for absorbance measurement.

Standard Stock solution

Accurately weighed 10 mg of diclofenac sodium standard was transferred to a volumetric flask and added sufficient water to produce 100 ml.

Sample Preparation

The four different brands (dicloran, defnac, artifin, voltral) were purchased from different medical store in Karachi. All the tablets of each brand had same batch number and were labeled to contain diclofenac sodium 50mg per tablet. All the three brands have 5 year shelf life.

The serial number as an identification of purchased brands are given in Tabel 1. Twenty tablets of four different brand of diclofenac sodium from the marketed sample were weighed and crushed uniformly with the help of a mortar and pestle. By calculating the average weighed sample powder equivalent to 10 mg of diclofenac sodium was transferred into a volumetric flask containing 10mL water. The solutions were sonicated for about 5 min and then 100 ml water was added.

Procedure

After preparation of standard and tablet solutions, strength of solution 100 ppm in 100 ml absorbance of the sample preparation and standard preparation in 1cm cell at the wavelength of maximum absorbance at about 340 nm, using a spectrophotometer, using the blank solution. Calculate the quantity in mg, of diclofenac sodium per tablet.

3. Results and Discussions

Pharmaceutical assay was carried out using spectrophotometer on all brands of diclofenac sodium tablets during the study. Table-1 shows name brand and % assay of different brands. Our results reveal that among all the four brands of diclofenac sodium (Dicloran, Defnac, Artifin, voltral) Defnac and voltral shows highest percentage assay 104% and Dicloran shows lowest value for percentage assay 96.4%, while artifin shows a percentage assay of 98.6%. Results also analysed by using SPSS software and the test used for analysis is ANOVA.

Test of hypothesis i-e ANOVA and multiple comparison of brands of diclofenac sodium

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Brand Name	Serial No.	Average wt of tablet mg	Wt for 100 ppm	Absorbance at 340nm	% assay
Dicloran	Dic-1	566	283	2.137	96.24
Defnac	Def-2	558	279	2.392	104
Artifin	Art-3	372	186	2.268	98.6
Voltral	Vol-4	448	224	2.398	104

Table 1: % Assay of different brands of Diclofenac sodium with absorbance and weight

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	0.232	3	0.077	4156.4	0
Within Groups	0	16	0		
Total	0.232	19			

Table 2: Descriptive statistics of different brands of Diclofenac sodium

(I) BRANDS	(J) BRANDS	Mean Difference (I-J)	Std. Error	Sig.	95% Confidence Interval	
					Lower Bound	Upper Bound
Dic-1	Def-2	-.25900*	.00273	.000	-.2648	-.2532
	Art-3	-.13020*	.00273	.000	-.1360	-.1244
	Vol-4	-.26060*	.00273	.000	-.2664	-.2548
Def-2	Dic-1	.25900*	.00273	.000	.2532	.2648
	Art-3	.12880*	.00273	.000	.1230	.1346
	Vol-4	-.00160	.00273	.566	-.0074	.0042
Art-3	Dic-1	.13020*	.00273	.000	.1244	.1360
	Def-2	-.12880*	.00273	.000	-.1346	-.1230
	Vol-4	-.13040*	.00273	.000	-.1362	-.1246
Vol-4	Dic-1	.26060*	.00273	.000	.2548	.2664
	Def-2	.00160	.00273	.566	-.0042	.0074
	Art-3	.13040*	.00273	.000	.1246	.1362

*. The mean difference is significant at the 0.05 level.

Table 3: Multiple Comparisons of different brands of Diclofenac sodium

are given in table 2,3 shows highly significant difference of diclofenac brands between groups and within groups. The proposed method for the assay of commercially available diclofenac sodium tablet formulation is very simple, accurate, least time consuming and rapid. It can be easily used for routine quality control QC for monitoring the assay in the API, in-process samples and tablet formulation. ANOVA shows between and within group F value 4156 with degree of freedom df value3 and 16 and p value 0.00 which shows significant results.

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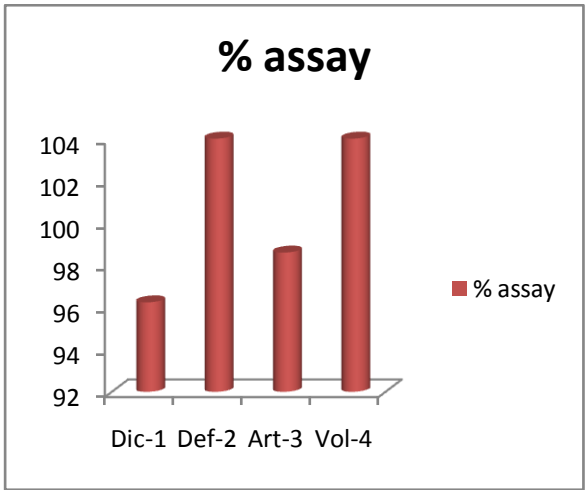


Figure 2 : % Assay of different brands of Diclofenac sodium

4. Conclusion

The proposed method is simple, precise, accurate, and selective for the estimation of diclofenac sodium in bulk and in tablet dosage forms. The method is economical, rapid and do not require any sophisticated instruments. Hence it can be effectively used for the routine analysis of diclofenac sodium in bulk and in tablet dosage forms.

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