International Journal for Multidisciplinary Research (IJFMR)
E-ISSN: 2582-2160 ● Website: www.ijfmr.com ● Email: editor@ijfmr.com

Development of Analytical Technique for Dichlofenac Sodium and Ibuprofen Utilizing UV Visible Spectroscopy and AUC Method

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Abstract

The purpose of this work was to create an analytical method combining UV visible spectroscopy and the AUC method for the simultaneous determination of diclofenac sodium and ibuprofen in their combination dosage form. The medications' UV spectra were captured between 200 and 400 nm, and the calibration curves were built using AUC values for diclofenac sodium and ibuprofen at 274 nm and 222 nm, respectively. The developed method's linearity, precision, accuracy, limit of detection, and limit of quantification were all validated in accordance with ICH recommendations. The findings demonstrated that the approach was linear, exact, accurate, and sensitive for the measurement of ibuprofen and diclofenac sodium. Without any excipient interference, the suggested approach was effectively used to determine the two medicines in their combination dose form. The created approach is straightforward, accurate, and cost-effective, and it may be utilised for regular analysis of ibuprofen and diclofenac sodium in their combination dose form.

Keywords: Dichlofinac sodium, ibuprofen, AUC, UV Spectroscopy, method Development

1.Introduction:

1.1. Analytical chemistry :

In the field of chemistry known as analytical chemistry, the components that make up a sample of matter are separated, identified, and their relative quantities are calculated. It mostly works on qualitative and quantitative analyses of substances as well as their detection. The identification of atomic or molecular species or functional groups in the sample can be determined using a qualitative approach. The relative amount of one or more of these components may be quantified using a quantitative approach, though. Analytical techniques are divided into two groups: classical techniques and instrumental techniques.

1.2. Specular imaging: A scientific field called spectroscopy examines how electromagnetic radiation interacts with stuff. The most significant result of this interaction is thatQuanta are finite amounts of energy that matter either absorbs or emits. Spectroscopy is among the most effective tools for the examination of atomic and molecular structure, which is used to a variety of sample analyses. The portion of the electromagnetic spectrum between 100 and 400 m is used in optical spectroscopy.

Figure no.1: Double Beam UV Spectrometer

1.3. Spectrophotometer for UV-Visible light

UV spectroscopy is a form of absorption spectroscopy in which a molecule absorbs light in the ultra-violet range (200-400 nm). Ultraviolet radiations that are absorbed cause the electrons to be excited from their ground state to a higher energy state. The energy difference between the ground state and higher energy states is equal to the energy of the ultraviolet light that is absorbed.

The Beer-Lambert law is the fundamental law that underlies quantitative spectrophotometric analysis.

A. Law of Beer:

According to this, the number of absorbing molecules causes the intensity of a parallel monochromatic radiation beam to go off exponentially. Thus, the relationship between absorbance and concentration is one of proportionality.

B. Lambert's Rule:

It claims that a parallel monochromatic radiation beam has an exponential loss in intensity as it travels through a homogenous thickness medium. The Beer-Lambert law is created when these two laws are combined.

Nonsteroidal anti-inflammatory medications (NSAIDs) including ibuprofen and diclofenac sodium are frequently used to treat pain, inflammation, and fever. Both drugs are extensively used, accessible either over-the-counter or by prescription, and they are frequently combined.

2. Instrumentation:

In order to treat inflammation, pain, and fever, nonsteroidal anti-inflammatory drugs (NSAIDs) like diclofenac sodium inhibit the synthesis of prostaglandins, which are chemicals that cause pain, inflammation, and fever. It is frequently used to treat inflammatory conditions including arthritis, menstrual cramps, and other forms of pain and discomfort. Tablets, capsules, gels, creams, patches, and other dosage forms are all options for diclofenac sodium.The NSAID ibuprofen also functions byLowering bodily pain and inflammation. It functions similarly to diclofenac sodium by lowering prostaglandin synthesis. Ibuprofen is frequently used to treat a variety of pain and inflammation,

including headaches, toothaches, menstrual cramps, and other conditions. The formulations come in tablet, pill, gel, cream, and liquid forms.

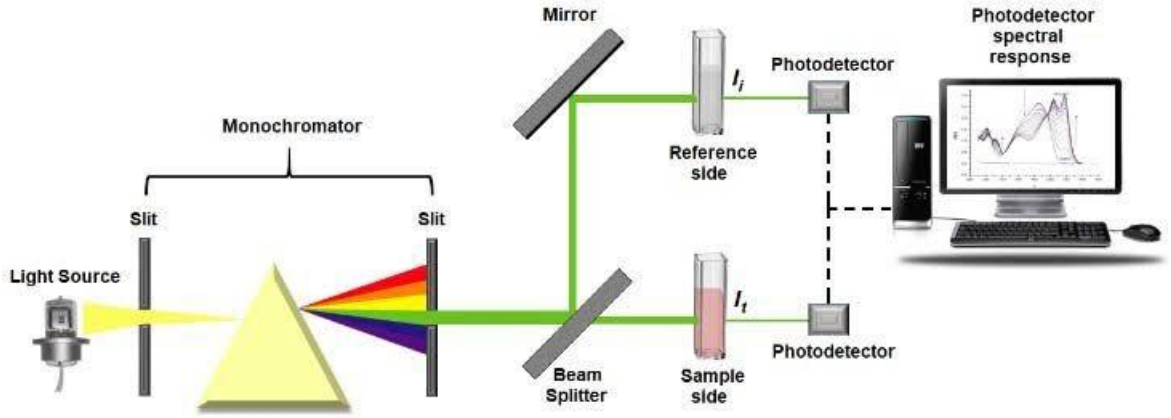


Figure no.2 : Working Of UV Spectrometer.

While both drugs work well to reduce pain and inflammation, there are some distinctions between them in terms of how they work, how they interact with other drugs, and how they cause adverse effects. For instance, gastrointestinal side effects including stomach ulcers and bleeding are more likely to occur with diclofenac sodium, but kidney issues and the symptoms of asthma are more likely to occur with ibuprofen.ibuprofen inflammation and pain management.Ibuprofen and diclofenac sodium are both significant drugs, and knowing their similarities and differences may help patients and healthcare providers choose the drug that is most suited to their requirements.

Molecular formula

Dichlofinac Sodium:- $C_{14}H_{10}C_{l2}NNaO_2$

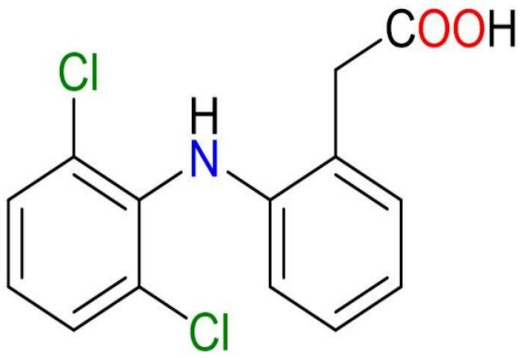
Ibuprofen:-$C_{13}H_{18}O_2$

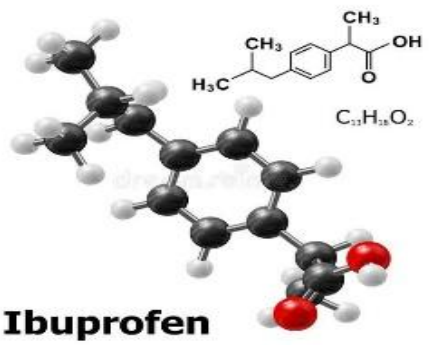
Molecular weight

Dichlofinac sodium:- 318.13 g/mol

Ibuprofen:- 206.29g/mol

Structure of Compounds *Dichlofinac sodium*





3. Material and Method:

3.1. Apparatus and Instrumentation

All spectral measurements were made using a shimadzu1800 UV/VISIBLE double beam spectrophotometer with 1 cm matched quartz cells. Weighing was done using a single pan electronic balance (CONTECH, CA 223, India). Utilising an Ultrasonic Cleaning Bath (Spectra lab UCB 40, India), the liquids were sonicated. For the validation investigation, calibrated volumetric glassware (Borosil®) was employed.

3.2. Material

Marksan Pharmaceutical Ltd., Verna, Goa, provided a gift sample of the reference standard for diclofenac sodium and Ibuprofen API. Sample tablets claiming 500 mg per tablet were bought from a local store in Pune.

4. Method development

4.1. Determination of wavelength Range

A. For Dichlofinac sodium

Diclofenac sodium 20 mg/ml solution was scanned in the spectrum mode from 400 nm to 200 nm against distilled water as a blank to determine the analytical wavelength range for the area under

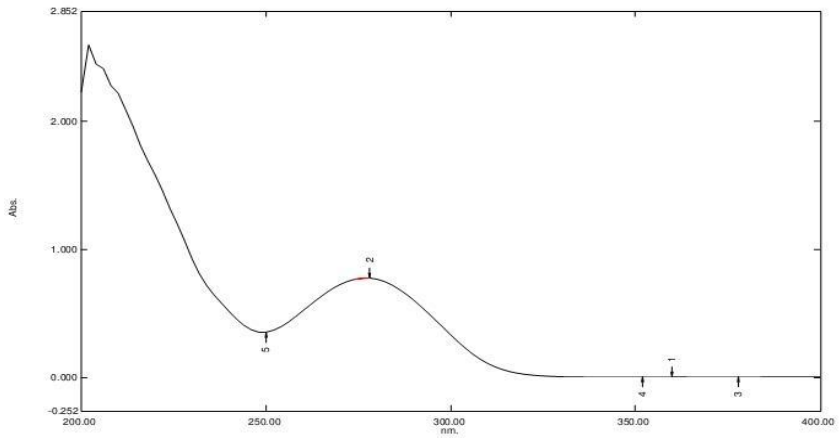


Figure no. 3. Sectrum of Dichlofenac Sodium

curve technique. The chosen wavelength range was centred on the wavelength maximum (276 nm). Between 05,10,15,20, and 25 g/ml, several working standards were created. On the basis of a linear connection between area and matching concentration, a final wavelength range between 270 and 282 nm was chosen after testing many other wavelength ranges.

B. For Ibuprofen

Ibuprofen solution (20 mg/ml) was scanned in the spectrum mode from 400 nm to 200 nm against distilled water as a blank to determine the analytical wavelength range for the area under curve technique. The wavelength range was chosen to include the maximum wavelength (222 nm). Various working standards in the range of 05–25 g/ml were created. A final wavelength range between 218 and

226 nm was chosen based on a linear connection after several different wavelength ranges were investigated.

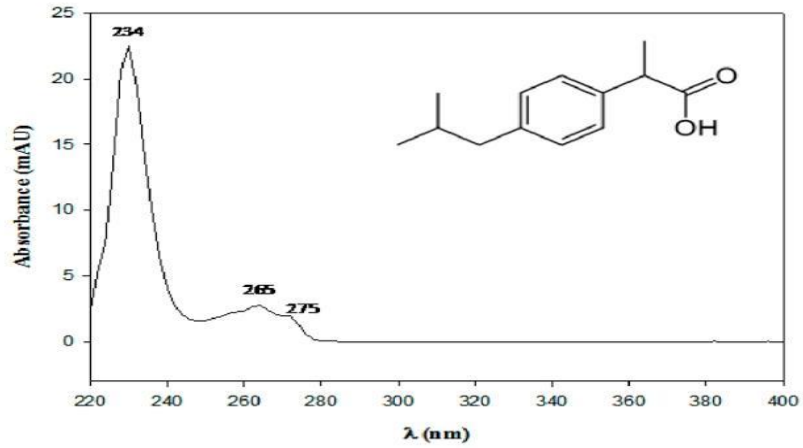


Figure no. 4: Spectrum Of Ibuprofen

4.2. Area Under Curve (Area Calculations)

With the area under curve technique, the start and end points of the curve region are represented by the integrated value of absorbance with respect to wavelength between two chosen wavelengths, such as λ1 and λ2. Using UV probe software, the area under the curve between λ1 and λ2 was computed. A wavelength integration between 227 and 282 nm was done in the research region.

Where, is the part of the diagram that is enclosed by the curve data and the straight line joining the start and finish points. Is the size of the region enclosed by a straight line joining the start and finish points on the curve data, andλ1 and λ2 are the start and end wavelength ranges of the curve region.

By calculating the integrated value of absorbance with respect to the wavelength between two chosen wavelengths, such as λ1 and λ2, which serve as the start and end points of the curve region, the area under the curve technique may be used to analyse data. We used UV probe software to determine the area under the curve between λ1 and λ2. An integrated wavelength range of 218 to 226 nm was used in this study region.

$$\text{Estimating the area: } (\alpha+\beta) = \int_{\lambda 2}^{\lambda 1} A d\lambda$$

Where, is the size of the section bounded by a straight line connecting the start and end point on the curve data, is the area of the portion circumscribed by a straight line connecting the start and end point on the curve data and the horizontal axis, and λ1 and λ2 are the wavelength range start and end points of the curve.

4.3. Preparation of Standard Solution

The standard stock solution of Diclofenac sodium was made by precisely weighing and adding 10 mg of API to a volumetric flask with 100 ml. The final standard stock solution (20 g/ml) was then diluted further with distilled water to produce 05–25 g/ml Diclofenac sodium solutions. Next, take 2 ml from that sample and put it to a 10 ml volumetric flask.

By precisely weighing and transferring 10 mg of API to a volumetric flask containing 100 ml, the

standard stock solution of ibuprofen was created. Take 2 ml of it and add it to a 10 ml volumetric flask with methanol to create the final standard stock solution (20 g/ml), which is then further diluted with methanol to create a 05–25 mg/ml Ibuprofen solution.

4.4. Calibration Curve

For Dichlofinac Sodium

The Standard Stock solution was diluted to obtain concentrations of 05, 10, 15, 20, and 25 g/ml, respectively. These solutions were scanned between 400 and 200 nm, with area under the curve (AUC) results integrated between 270 and 282 nm. Against concentration, the calibration curve was drawn between areas under the curve values.

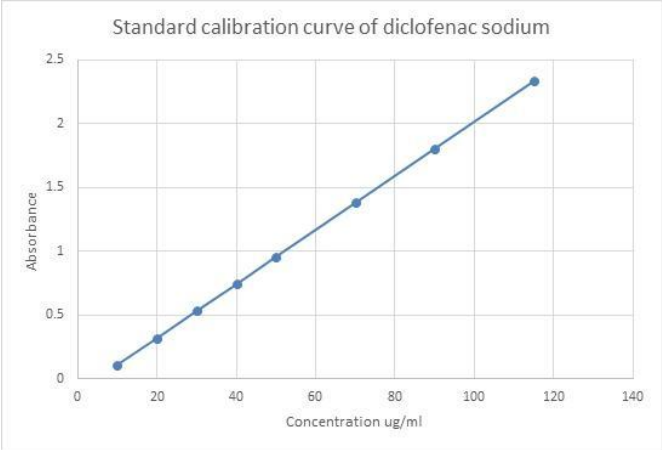


Figure no. 5. Liniarity of Dichlofenac Sodium

For Ibuprofen

The Standard Stock solution was diluted to obtain concentrations of 05, 10, 15, 20, and 25 g/ml, respectively. These solutions were scanned between 400 and 200 nm, with area under the curve (AUC) results integrated between 218 and 226 nm. Figure 3 shows the calibration curve drawn between areas under the curve values and concentration. Examining Tablet Formulation Twenty 500 mg Ibuprofen pills were weighed after being crushed to powder, and the average weight was computed. Ibuprofen 10 mg worth of powder was placed into a 100 ml volumetric flask. Methanol 50 ml was added, and it was sonicated for 15 minutes. Then, more Methanol was added to the solution to dilute it to the proper level.

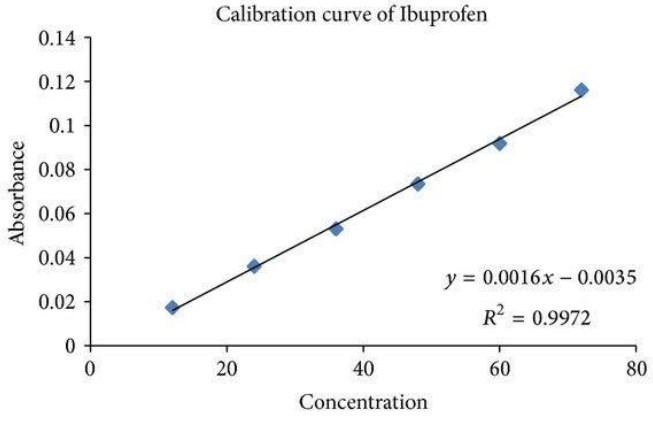


Figure no .6. Liniarity of Ibuprofen

The whatman filter paper no. 41 was used to filter the solution.First, 5 cc of the filtrate were thrown away. This solution was further diluted to obtain 15 g/ml of methanol-based solution, which was then submitted to UV analysis using methanol as a blank. Three times this process was done.

5. Assay of Tablet Formation

A. For Dichlofinac sodium

The average weight of 20 pills, each of which contained 500 mg of diclofenac sodium, was computed. 100 cc of volumetric flask received powder equating to 10 milligrammes of diclofenac sodium. 50ml of distilled water was added, and 15 minutes of sonication followed.The solution was then further diluted with distilled water till the desired consistency. The first 5 ml of the filtrate were discarded after the solution was filtered using Whatmannfilter paper no.41.This solution was further diluted to obtain 15 g/mL of solution with water, which was then used as a blank for UV analysis. Three times this surgery was carried out.

Table no. 1. Assay of Tablet Dosage Form.

Sr.No.	Sample solution concentration(µg/ml)	Amount found (%)*	Mean % found	% RSD
1.	15	100.22		
2.	15	99.49	99.25	0.5672
3.	15	98.04		

**n=3, SD= Standard Deviation, % RSD=%Relative Standard Deviation.*

For Ibuprofen

Ibuprofen 500 mg pills weighing 20 were crushed to powder, and the average weight was determined. A 100 ml volumetric flask was filled with powder that was 10 mg of Ibuprofen equivalent. After adding 50 ml of methanol, the mixture was sonicated for 15 minutes. Following that, Methanol was used to further dilute the solution until it reached the desired concentration. Whatman filter paper no. 41 was used to filter the solution; the first 5 ml of filtrate were discarded. Using methanol as a blank, this solution was further diluted to produce a 15 g/ml solution, which was then exposed to UV analysis. This process was carried out three times.

Table no. 2. Assay of Tablet Dosage Form.

Sr.No.	Sample solution concentration(µg/ml)	Amount found (%)*	Mean % found	% RSD
1.	15	98.59		
2.	15	100.07	99.28	0.5810
3.	15	99.19		

**n=3, SD= Standard Deviation, % RSD=% Relative Standard Deviation.*

6. Discussion:

Nonsteroidal anti-inflammatory medications (NSAIDs) including diclofenac sodium and ibuprofen are frequently used to treat pain, inflammation, and fever. There are some significant distinctions between

the two medications, even though they both function by preventing the formation of prostaglandins, which are in charge of generating pain and inflammation.Diclofenac sodium is frequently used to treat more intense pain and inflammation since it is usually thought to be more powerful than ibuprofen. It is a flexible alternative for different sorts of pain management because it is also offered in a variety of forms, including oral tablets, injectable solutions, and topical gels.Contrarily, ibuprofen is frequently used to treat moderate pain and inflammation, including headaches, menstrual cramps, and small injuries. It is more accessible than diclofenac sodium, which needs a prescription, as it is also sold over-the-counter.Despite their similarities, both medicines have potential negative effects, especially if used over a prolonged period of time. Gastrointestinal issues including stomach ulcers and bleeding, as well as cardiovascular issues like an elevated risk of heart attack and stroke, are common adverse effects. Patients should exercise caution when taking either medication and should speak with their doctor if they have a history of digestive or cardiovascular issues.

7. Conclusion:

In conclusion, both diclofenac sodium and ibuprofen are effective NSAIDs that can provide pain relief and reduceInflammation. However, the choice of drug will depend on the severity of the pain and the patient's medical history. As with all medications, it is important to use these drugs under the guidance of a healthcare professional and to be aware of the potential side effects.

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