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Development and Method Validation for Estimation of Ibuprofen by Area Under Curve Method

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Abstract: *A UV visible spectrophotometric approach that is easy to use, precise, accurate, and affordable has been devised for the AUC method of ibuprofen drug measurement. Double-distilled water was used as a solvent in the preparation of the standard and sample solutions. The drug's quantitative determination was carried out in the wavelength region of 218–226 nm. Ibuprofen's linearity was demonstrated with a correlation coefficient value of 0.999 for the concentration range of 5–25 µg/ml. According to precision studies, the percentage relative standard deviation fell within the permissible bounds. The average recovery percentage was discovered to be 99.79%. The suggested approach has been verified in accordance with ICH regulations.*

Keywords: NSAID, ibuprofen, assay, UV spectrophotometry, AUC, electromagnetic radiation, Accuracy, precision studies, linearity.

I. INTRODUCTION

Analytical method development and validation involves a series of activities that are ongoing during life cycle of drug product and drug substances. As the myriad of chemical and physical test provide results concerning the purity, potency, identity, efficacy, physical characteristic and overall quality of drug substance and drug product which are integral part of drug development and commercialization strategy as it moves through the new drug life cycle.

The pharmaceutical industry have to produce quality of drug in pharmaceutical dosage form must be carefully controlled as a minor change in purity of drug may affect the therapeutic value. The efficacy and safety of a medicinal product can only be assured by analytical monitoring of its quality. Therefore the overall purity of a medicine must be assessed throughout its storage, distribution and use. This objective can possibly be achieved if the specifications to be applied are based on a validated procedure which can demonstrate the relationship in quality between the substance under examination and that initially subjected to pharmaceutical, toxicological and pharmacological evaluation.

The sound quality control will always depend on the use of valid analytical procedure. Method validation is the process of documenting or proving that an analytical method provides analytical data acceptable for the intended use. The validation is absolutely essential whether the procedure is intended to be applied within a manufacturing company, within a government control laboratory or proposed to be included in pharmacopoeia.

Ultraviolet-visible spectroscopy is a common analytical technique for qualitative and quantitative analysis of solid, liquid or gas samples. Ultraviolet-visible spectroscopy (UV = 200-400 nm, visible 400-800 nm) corresponds to electronic excitations between the energy levels that correspond to the molecular orbital's of the systems.

Absorption of light in both UV & visible region of electromagnetic spectrum occur when the energy of light matches that required to induce in the molecule an electronic transitions. The intensity of the absorbance is detected by beer's law. The light absorbed by sample can be calculated and provides a very sensitive and reproducible means for determining the concentration of absorbing species.

Spectrophotometric is a quantitative method of analysis involving the principles associated with how visible light interacts with atoms. Visible light is a small portion of the electromagnetic spectrum and includes the colours we observe (red, orange, yellow, green, blue and violet). It consists of electromagnetic radiation whose wavelengths range from 400- 700 nm.

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ANALYTICAL METHOD VALIDATION:

Method validation is the process of providing an analytical method that is acceptable for its intended purpose. For pharmaceutical methods, guidelines from the International Conference on Harmonization (ICH) and the Food and Drug Administration (FDA) provide a framework for performing such validations. In general, methods for regulatory submission must include studies on specificity, linearity, accuracy, precision, range, detection of limit, quantification of limit, & robustness.

OBJECTIVE:

The objective of any analytical measurement is to obtain consistent, reliable and accurate data. Validated analytical methods play a major role in achieving this goal. The results from method validation can be used to judge the quality, reliability and consistency of analytical results, which is an integral part of any good analytical practice. Validation of analytical methods is also required by most regulations and quality standards that impact laboratories.

- Precision
- Accuracy
- Limit of Detection
- Limit of Quantitation
- Specificity
- Linearity and Range
- Method Validation

ACCURACY:

Accuracy is the measure of exactness of an analytical method, or the closeness of an agreement between the values, which is accepted either as a conventional, true value or an accepted reference value and the value found. It is measured as the percent of analyte recovered by assay, by spiking samples in a blind study. For the assay of the drug substance, accuracy measurements are obtained by comparison of the results with the analysis of a standard reference material, or by comparison to a second, well-characterized method. To document.

PRECISION:

Precision is the measure of the degree of repeatability of an analytical method under normal operation and is normally expressed as the percent relative standard deviation for a statistically significant number of samples. According to the ICH, precision should be performed at three different levels: repeatability, intermediate precision, and reproducibility. Repeatability is the results of the method operating over a short time interval under the same conditions (inter- assay precision). It should be determined from a minimum of nine determinations covering the specified range of the procedure (for example, three levels, three repetitions each) or from a minimum of six determinations at 100% of the test or target concentration. Intermediate precision is the result from within lab variations due to random events such as different days, analysts, equipment, etc. In determining intermediate precision, experimental design should be employed so that the effects (if any) of the individual variables can be monitored.

Documenting Precision Reproducibility refers to the results of collaborative studies between laboratories. Documentation in support of precision studies should include the standard deviation, relative standard deviation, coefficient of variation, and the confidence interval.

SPECIFICITY:

Specificity is the ability to measure accurately and specifically the analyte of interest in the presence of other components that may be expected to be present in the sample matrix. It is a measure of the degree of interference from such things as other active ingredients, excipients, impurities, and degradation products, ensuring that a peak response is due to a single component only i.e. that no co-elution exist.

Specificity is measured and documented in a separation by the resolution, plate count (efficiency), and tailing factor. Specificity can also be evaluated with modern photodiode array detectors that compare spectra collected across a peak

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mathematically as an indication of peak homogeneity. ICH also uses the term specificity, and divides it into two separate categories: identification, and assay/impurity tests.

LIMIT OF DETECTION:

The limit of detection (LOD) is defined, as the lowest concentration of an analyte in a sample that can be detected but not quantified. It is a limit test that specifies whether or not an analyte is above or below a certain value. It is expressed as a concentration at a specified signal-to- noise ratio, usually two- or three-to-one.

The ICH has recognized the signal-to-noise ratio convention, but also lists two other options to determine LOD: visual non-instrumental methods and a means of calculating the LOD. Visual non-instrumental methods may include LOD's determined by techniques such as thin layer chromatography (TLC) or titration. LOD's may also be calculated based on the standard deviation of the response (SD) and the slope of the calibration curve (S) at levels approximating the LOD according to gula: LOD = 3.3(SD/S).

LIMIT OF QUANTIFICATION:

The Limit of Quantitation (LOQ) is defined as the lowest concentration of an analyte in a sample that can be determined with acceptable precision and accuracy under the stated operational conditions of the method. Like LOD, LOQ is expressed as concentration, with the precision and accuracy of the measurement also reported. Sometimes a signal-to-noise ratio of ten-to-one is used to determine LOQ. This signal-to-noise ratio is a good rule of thumb, but it should be remembered that the determination of LOQ is a compromise between the concentration and the required precision and accuracy. That is, as the LOQ concentration level decreases, the precision increases. If better precision is required, a higher concentration must be reported for LOQ. This compromise is dictated by the analytical method and its intended use.

The ICH has recognized the ten-to-one signal-to-noise ratio as typical, and also, like LOD, lists the same two additional options that can be used to determine LOQ, visual non-instrumental methods and a means of calculating the LOQ. The calculation method is again based on the standard deviation of the response (SD) and the slope of the calibration curve (S) according to the formula.

LINEARITY AND RANGE:

Linearity is the ability of the method to elicit test results that are directly proportional to the analyte concentration within a given range. Linearity is generally reported as the variance of the slope of the regression line. Range is the interval between the upper and lower levels of analyte (inclusive) that have been demonstrated to be determined with precision, accuracy and linearity using the method as written.

NEED AND OBJECTIVE OF PRESENT INVESTIGATION:

A number of drugs are introduced in the market every year. Pharmaceutical products formulated with single drug or in combination, are intended to meet previously unmet patients need and to action better therapeutic effects. These products can present daunting challenges to the analytical chemist responsible for the development and validation of analytical methods. To consider the quality of the product and to carry out the analysis of the content without separating or extracting became today's need, because such processes of extraction or separation are time consuming, tedious and always costlier. Therefore it is necessary to develop a rapid, accurate and reproducible method to estimate the drug concentration in presence of other drugs, chemicals, excipients etc.

Many times new products do not have any official methods for analysis of their "active pharmaceutical ingredients". This is because there is a time lag between the introduction of the drug into the market and its inclusion in the pharmacopoeias. Hence, it becomes necessary to develop newer analytical methods for routine analysis of these drugs which will help to ensure the identity, purity, potency and performance of the drugs in the dosage forms. Also the ICH guidelines further amplify the need for method development of new formulations thus the present work is undertaken with an aim to meet these challenges of analytical chemists regarding the new drugs and their formulations.

Thus, analytical method development plays an important role in the discovery, development, and manufacture of pharmaceuticals and to establish standards for their purity, quality and identity, this justifies the importance for

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developing new analytical methods which can be used for RED) Mity bestrel and quality assurance of drug formulations.

Ibuprofen commonly used for the treatment of hypertension. Quality of drug in pharmaceutical dosage form must be carefully controlled as a minor change in purity of drug may affect the therapeutic value. As there is vast development in pharmaceutical products, there is need to develop the sensitive and precise analytical techniques. The developed method should be simple and precise and should be applicable for estimation of drug in pharmaceutical de and form. This method can be conventionally used for quality control and routine analysis of drugs in pharmaceutical dosage forms in pharmaceutical industries and research laboratories.

Literature survey has revealed that there are very few RP-HPLC methods are reported for estimation of perindopril erbumine individually. No difference spectrophotometric method reported for estimation PDE in bulk and pharmaceutical formulation. Few reported spectrophotometry method for estimation of PDE in bulk and tablet dosage and also there is no any method reported for colorimetric estimation of PDE in tablet dosage form by using ferric chloride and potassium Ferricyanide.

Thus present work is an attempt to develop rapid, precise, simple, economic and accurate and less consuming UV-Spectrophotometric and chromatographic method for estimation of drug in bulk and pharmaceutical dosage form.

OBJECTIVE OF PRESENT INVESTIGATION:

The study makes an attempt to establish sensitive and accurate analytical method for estimation of perindopril erbumine in bulk and pharmaceutical dosage form.

1. To develop analytical method for active pharmaceutical ingredient (API) in dosages form.
2. To develop newer analytical methods of perindopril erbumine by spectrophotometry and chromatography.
3. To Validate and develop analytical method as per ICH guidelines.

PLAN OF WORK:

1. Literature Review.
2. Set of drug, chemicals and dosage form.
3. Determination of solubility of drug in different solvents.
4. Selection of analytical techniques.
1. UV. Spectrophotometry.
5. Development and validation analytical techniques as per ICH (Q2B) guidelines.

a) Estimation of Ibuprofen by UV Spectrophotometric Method Involving Following Steps: Selection of common solvent.

b) Study of spectra.

c) Selection of method and wavelength.

6. Data analysis
7. Writing of records.

DRUG PROFILE:

PHARMACOKINETICS:

- Absorption:The area under the plasma concentration-time curve (AUC) of ibuprofen is dose-dependent. Ibuprofen binds extensively, in a concentration-dependent manner, to plasma albumin.
- Distribution: The apparent volume of distribution of ibuprofen - Ibuprofen dosage is more than 99% bound to plasma proteins and site II of purified albumin, binding appears to saturable and becomes non-linear at concentrations exceeding 20 mcg/ml.
- Metabolism:It is rapidly bio-transformed with a serum half life of 1.8 to 2 hours. The drug is completely eliminated in 24 hours after the last dose and eliminated through metabolism. The drug is more than 99% protein bound, extensively metabolized in the liver and little is excreted unchanged.

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- Excretion: Ibuprofen is eliminated following biotransformation to glucuronide conjugate metabolites that are excreted in urine, with little of the drug being eliminated unchanged. The excretion of conjugates may be tied to renal function and the accumulation of conjugates occurs in end-stage renal disease.

II. LITERATURE REVIEW

ULTRAVIOLET-VISIBLE ABSORPTION SPECTROSCOPY

Spectroscopy is the branch of science dealing with the study of interaction of electromagneticradiation with matter. It is the most powerful tool available for the study of atomic and molecular structure and is used in the analysis of a wide range of samples.

A simple, precise, accurate, and economical UV visible spectrophotometric method has been developed for estimation of ibuprofen drug by AUC method. The standard and sample solutionswere prepared by using double distilled water as a solvent. Quantitative determination of the drug was performed at wavelength range 218-226 nm. The linearity was established over the concentration range of 5-25 µg/ml for ibuprofen with correlation coefficient value of 0.999. Precision studies showed that % relative standard deviation was within range of acceptable limits. The mean percentage recovery was found to be 99.79%. The proposed method has beenvalidated as per ICH guidelines.

1. Gall EP, Caperton EM, McComb JE, Messner R, Multz CV, O'Hanlan M, et al 1982. Analytical method development and validation involves a series of activities that are ongoingduring life cycle of drug product and drug substances. As the myriad of chemical and physical test provide results concerning the purity, potency, identity, efficacy, physical characteristicand overall quality of drug substance and drug product which are integral part of drugdevelopment and commercialization strategy as it moves through the new drug life cycle **2.Senekjian HO, Lee C, Kuo TH, Krothapalli R. 1983**

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Herzfeld CD, Kummel R 1983

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Compreton EL, Glass RC, Hird ID. 1984

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Ross JM, De Horatius J. 1990

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Calrk WG, Brater DC, Jhonson AR.. 1992

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Katzung BG, Furst DE1998

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Nuki G, Ralston SH, Luqmani R 1999

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Winstanley P, Walley T. 2002

The majority of the world's population may easily obtain ibuprofen in convenient forms for use over-the-counter. Oral capsules, oral suspensions, oral tablets, chewable tablets, intravenous solutions, topical gels, and combination kits are examples of common dose forms**12.Chavez ML, DeKorte CJ. Clin Ther 2003**

III. CHEMICAL STRUCTURE OF IBUPROFEN

Chemically speaking, (RS)-2-(4-(2-methylpropyl)phenyl) propanoic acid is ibuprofen. Although ibuprofen is known to have an antiplatelet effect, this impact is very weak and somewhat transient when compared to other antiplatelet medications such as aspirin. Since it inhibits the vasodilating prostacyclin produced by cyclooxygenase 2 enzymes, ibuprofen has been demonstrated to constrict coronary arteries and certain other blood vessels. In general, ibuprofen also functions as a vasoconstrictor. [1] Several analytical techniques, including UV spectrophotometry [2] and HPLC [3], have been reported in bulk pharmaceutical dosage form for the measurement of Ibuprofen, according to a literature review. As far as we are aware, no UV spectrophotometric technique employing Area under Curve (AUC) has been documented for ibuprofen quantification in tablets and bulk form. Thus, an effort to create new UV spectrophotometry has been made.

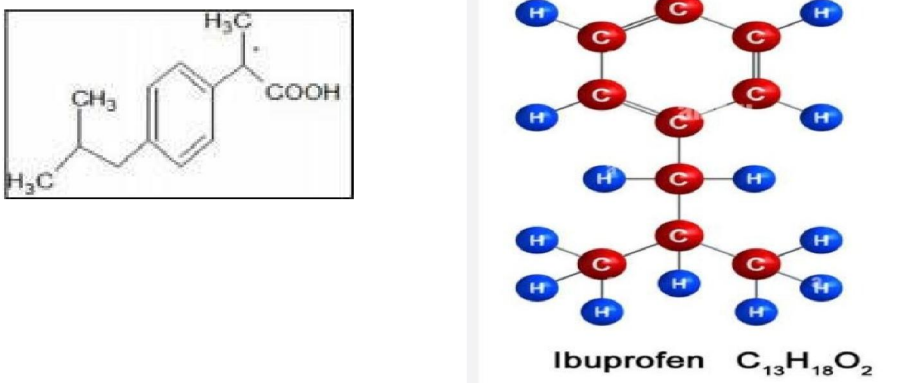

Figure 1: The structural formula of ibuprofen

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ADMINISTRATION:

The majority of the world's population may easily obtain ibuprofen in convenient forms for use over-the-counter. Oral capsules, oral suspensions, oral tablets, chewable tablets, intravenous solutions, topical gels, and combination kits are examples of common dose forms. When takinga medication orally, it is typically advised that adults and children take it with food or milk. When oral delivery is not possible or is not convenient, IV administration is frequently used in inpatient settings. The infusion should last at least 30 minutes for adults and 10 minutes for paediatric patients.

An IV preparation that is frequently used is ibuprofen with lysine. Although total parenteral nutrition may still be used in the same manner, ibuprofen should not be given in conjunction with it. Instead, total parenteral feeding should be stopped for fifteen minutes prior to and following ibuprofen administration. Emerging studies aim to investigate the potential of administering ibuprofen and other IV drugs or nutrients at the same time. The physical and chemical compatibility of IV ibuprofen infusion with two distinct total parenteral nutrition formulations in neonates with PDA was demonstrated in a 2018 study investigating the chemical compatibility of continuous ibuprofen lysine infusion with total parenteral nutrition.

ADVERSE EFFECTS:

One well-known side effect of taking ibuprofen is bleeding into the stomach, which can result in ulcers, bleeding, perforations, or gastritis. When ibuprofen is used, COX isoform inhibition results in a decrease in prostaglandins, which are involved in the release of mucus that protects the stomach. Non-selective NSAIDs exhibit a more marked effect on this phenomenon, whereas COX-2 selective NSAIDs exhibit a reduced frequency of gastrointestinal problems, a particularly concerning finding for paediatric patients. Because ibuprofen is quite safe when compared to other medications in its class, its use is higher than that of other NSAIDs. Ibuprofen over-the-counter use without a prescription raises the danger of high dosage levels and short interval dosing intervals, both of which might hasten gastrointestinal problems.

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CONTRAINDICATION:

Patients having a history of recognised hypersensitivity or allergic responses to aspirin, other NSAIDs, or the medication itself should not take ibuprofen. Several case studies describe ibuprofen as a cause of post-usage illness.Among the most common drug classes linked to hypersensitivity reactions are NSAIDs. In both adult and paediatric populations, urticaria/angioedema resulting from cross-intolerance to other drug classes, including quinolones and amoxicillin-clavulanic acid, is the most common diagnosis. Studies conducted on NSAID-induced hypersensitivity reactions in children revealed that while the frequency was similar, the clinical characteristics varied. The gold standard for identifying NSAID hypersensitivity is still oral provocation testing; safe substitutes for children and adolescents who are cross-intolerant include tolmetin, etoricoxib, paracetamol, and nimesulide.

Ibuprofen lysine IV formulation is contraindicated in premature infants with proven or suspected necrotizing enterocolitis, active bleeding, thrombocytopenia, renal impairment, and congenital heart disorders necessitating patency of the PDA. Apart from this, it has been demonstrated that ibuprofen does not have any more side effects when administered to infants under the age of six months, and it is still recommended for usage in paediatric populations when these contraindications are met. Drug labels for ibuprofen in Canada mention contraindications for a

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number of other disorders, such as uncontrolled heart failure, lupus, renal impairment, hepatic impairment or illness, and active gastrointestinal or cerebrovascular bleeding.

PREFORMULATION:

Studies for preformulation

The physicochemical characterization of the medication and excipients that are helpful in preparing the dosage form are included in the preformulation studies.

Characters with organoleptic traits This involves documenting the drug's colour, taste, and odour. The colour record is particularly helpful in determining the right batch size.

DENSITY:

May affect a powder's flow, compressibility, solubility, and other characteristics.

BULK DENSITY:

A measurement used to characterise a particle packing is called bulk density. It was calculated using a measuring cylinder and balance, and the result is (gm/ml). The measuring cylinder's weight was first tarred. Next, a funnel was used to transfer 4 gm of presieved (40#) bulk medication into the measurement cylinder. Next, the powder's volume was measured. The granules' bulk density was determined using the formula below.

Bulk density = Weight of powder / Volume of powder.

ANGLE OF REPOSE:

Angle of repose is the tan inverse of angle between height (h) of pile of powder and the radius (r) of the base of conical pile. It can be obtained between the freestanding surface of the powder heap and the horizontal plane. The fixed funnel that is secured with its tip at a given height h, above graph paper, placed on the flat horizontal surface. Powder is carefully poured through funnel until the apex of conical pile just touches the tip of funnel.

SOLUBILITY STUDIES:

Aqueous solubility of NSAID as a function of pH was determined in different physiological media. Solubility of drug was studied at different Ph range i.e. pH 1.2 (0.1 N HCl), Ph 4.5 (Phosphate Buffer), pH 6.8 (Phosphate Buffer), pH 7.4(Phosphate Buffer)

APPEARANCE:

A random selection of tablets from each formulation were used to assess the organoleptic characteristics, including colour, taste, and shape.

HARDNESS TEST:

For simple disintegration in the mouth, fast-dissolving pills often have a low hardness. A Shulinger hardness tester was used to measure the hardness.

IV. MATERIAL AND METHODS

APPARATUS AND INSTRUMENTATION:

All spectrum measurements were performed using a shimadzu 1800 UV/VIS double beam spectrophotometer equipped with quartz cells that were matched to the centimetre. Weighing was done using a single pan electronic balance (CONTECH, CA 223, India). Using an Ultrasonic Cleaning Bath (Spectra lab UCB 40, India), the solutions were sonicated. The validation investigation employed Borosil® calibrated volumetric glassware.

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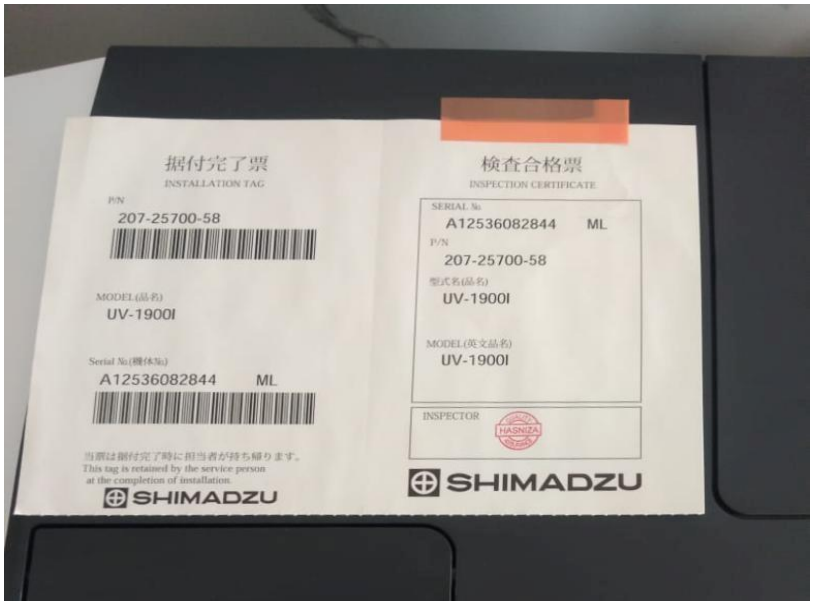

MATERIAL:

Jay ganesh pharmaceuticals sadashivpeth pune, provided a gift sample of the reference standard for Ibuprofen API. Samples of tablets, each claiming to contain 500 mg, were bought from a local Pune market.

DETERMINATION OF WAVELENGTH RANGE:

To determine the analytical wavelength range for the area under curve method, a 20 µg/ml solution of Ibuprofen was scanned in spectrum mode, with distilled water serving as a blank, from 400 nm to 200 nm. Around the wavelength maxima (222 nm), the wavelength range was chosen. A range of working standards, from 05 to 25 µg/ml, were prepared. After experimenting with a range of wavelengths, the final range between 218 and 226 nm was chosen based on the linear relationship between the concentration and area.

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EXPERIMENTAL INVESTIGATION:

AREA UNDER CURVE(AREA CALCULATION):

The area under the curve method computes the integrated absorbance with respect to wavelength between two chosen wavelengths, such as λ1 and λ2, which indicate the curve region's start and end points. Using UV probe software, the area under curve between λ1 and λ2 was computed. This research area integrated wavelength bands ranging from 218 to 226 nm.

Calculating area: $(\alpha+\beta) = \acute{a}\lambda 1\ Ad\lambda$

where λ1 and λ2 are the wavelength range start and end points of the curve region, α is the area of portion defined by curve data and a straight line connecting the start and end point, andβ is the area of portion circumscribed by a straight line connecting the start and end point on curve data and horizontal axis.

PREPRATION:

Ibuprofen's standard stock solution was made by precisely weighing and adding 10 mg of APIto a 100 ml volumetric flask. Next, remove 2 millilitres from that and put it in a 10-milliliter volumetric flask. Then, add methanol to form the final standard stock solution (20 µg/ml).

PROCEDURE FOR PLOTTING CALIBRATION CURVE:

From standard stock solution of drug, six working standard solutions prepared and scanned inthe wavelength range of 200-400 nm. The appropriate aliquots of drug were pipette out from standard stock solution of the drug in methanol: water (70:30) into series of 10 ml volumetric flask. The volume was made up to get solution of concentration 3, 6, 9, 12, 15 and 18 of PDE in methanol: water (70:30). Calibration curve was constructed at wavelength 210 nm by recording absorbance against concentration of drug PDE obeyed Beer's law in the concentration range of 3-18~\mu g/ml By using quantitative modes of instrument slope, intercept and correlation coefficient values for calibration curve was obtained. The concentration of PDE was calculated by using formula: Y=mx+c where m=0.066 c=0.009 x= concentration of PDE and correlation coefficient for PDE was 0.998 was then diluted with methanol to produce solutions containing 05–25 µg/ml of Ibuprofen.

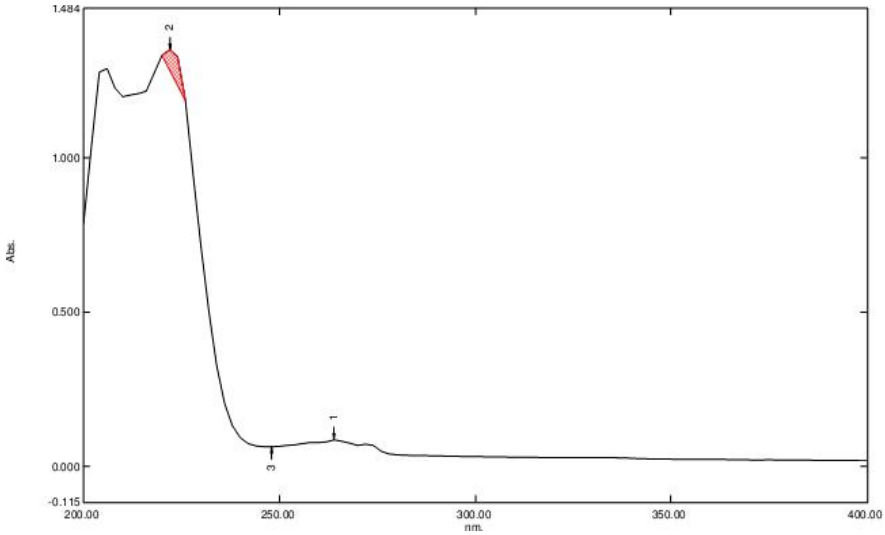

Figure 2: UV AUC spectrum of ibuprofen (20 µg/ml)

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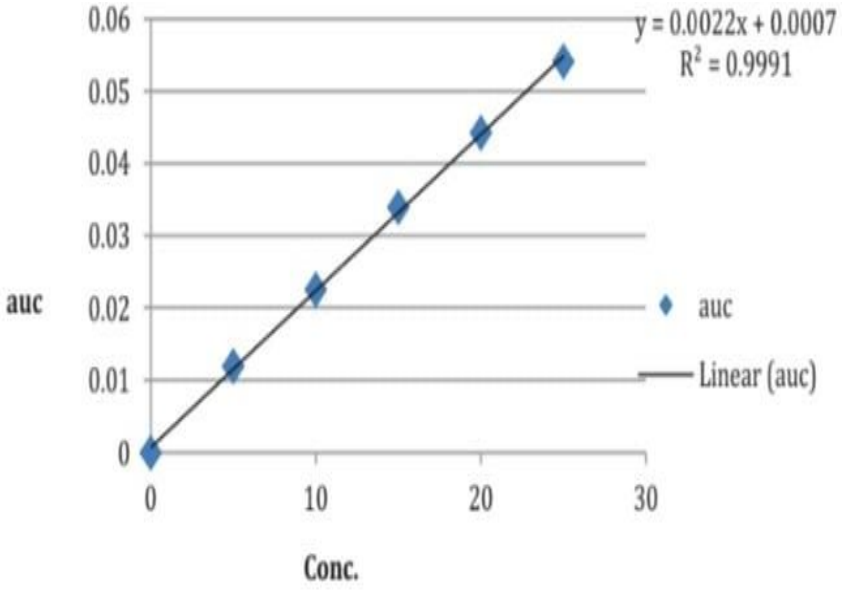

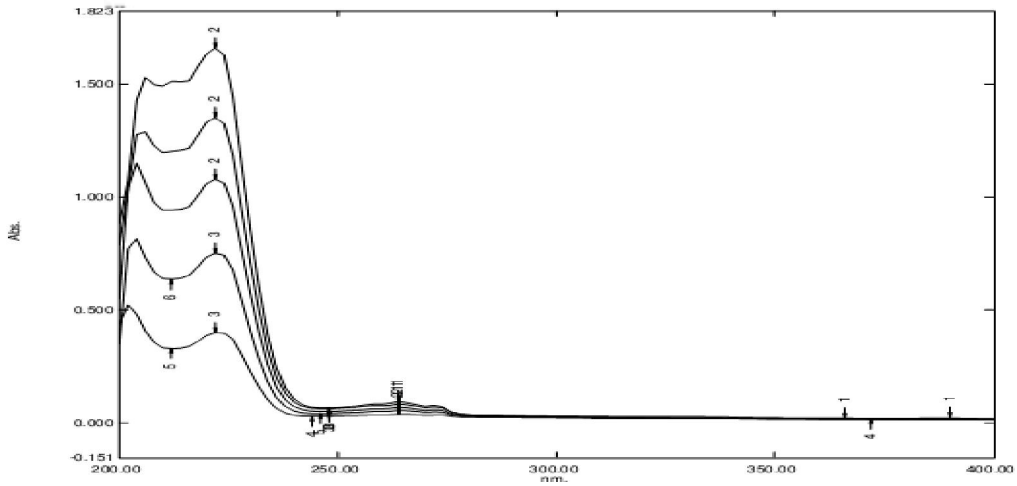

Figure 4: Overlay of Ibuprofen spectra at different concentration

CALIBRATION CURVE FOR IBUPROFEN:

The Standard Stock solution was diluted to obtain concentrations of 5, 10, 15, 20, 25, and 0.5 µg/ml, in that order. The area under the curve (AUC) measurements for these solutions were integrated between 218 and 226 nm after they were scanned from 400 to 200 nm. Plotting the calibration curve versus concentration between areas under the curve values was done.

ASSAY OF TABLET FORMULATION:

After twenty 500 mg Ibuprofen tablets were crushed and weighed, the average weight was computed. Ibuprofen 10 mg worth of powder was added to a 100 ml volumetric flask. They added 50 millilitres of methanol and sonicated for fifteen minutes. Subsequently, methanol was added to the solution to dilute it even further. Using Whatman filter paper No. 41, the solution was filtered; the first 5 millilitres of the filtrate were thrown away. This solution was further diluted with methanol to get a 15 µg/ml solution, which was then used as a blank for UV analysis. Three iterations of this process were carried out.

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Sr no.	Sample solution concentration	Amount found	Mean % found	%RSD
1.	15	98.59		
2.	15	100.07	99.28	0.5810
3.	15	99.19		

Accuracy result for ibuprofen

Accuracy level	Sample concentration	Standard concentration	Total amount added	% Recover	Mean %	%RSD
80	15	12	27	99.63		
100	15	15	30	100.91	99.79	1.8032
120	15	18	33	98.84		

Precision result for ibuprofen

Parameter	Intra-day	Inter-day
Sample solution concentration	20	20
AUC mean	0.2251	0.3348

Summary of validation parameter

V. EXPERIMENTAL RESULT AND DISCUSSION

It was discovered that the area under the curve approach for ibuprofen using UV visible spectroscopy was straightforward, accurate, affordable, and repeatable. The devised method demonstrated linearity, as indicated by the correlation coefficient value of 0.999, and the drug concentrations were determined to be linear within the 05–25 µg/ml range. The approach was deemed precise as the percent relative standard deviation (% RSD) for accuracy was determined to be 0.5810, while the percent relative standard deviation values for intra-day and inter-day precision were found to be 0.2251 and 0.3348, respectively.

Recovery experiments were used to evaluate the method's accuracy at three different levels: 80%, 100%, and 120%. The recovery studies were nearly 100%, and the standard deviation figures were acceptable. The method's accuracy is indicated by the % RSD value of less than

It was discovered that the limits of quantitation and detection were 2.9239 and 0.9677 µg/ml, respectively. The developed method's analysis for pharmaceutical formulation produced highly reproducible and trustworthy results that aligned with the label claim. Table 4 provides an overview of the validation parameters. The technique can be applied to pharmaceutical formulations and bulk ibuprofenin for routine quality control analysis.

SUMMARY:

A UV visible spectrophotometric approach that is easy to use, precise, accurate, and affordable has been devised for the AUC method of ibuprofen drug measurement. Double-distilled water was used as a solvent in the preparation of the standard and sample solutions. The drug's quantitative determination was carried out in the wavelength region of 218–226 nm. Ibuprofen's linearity was demonstrated with a correlation coefficient value of 0.999 for the concentration range of 5–25 µg/ml. According to precision studies, the percentage relative standard deviation fell within the permissible bounds. The average recovery percentage was discovered to be 99.79%. The suggested approach has been verified in accordance with ICH regulations.

CONCLUSION:

The assessment of bulk drugs and pharmaceutical dose formulations can be performed using the straightforward, accurate, and exact UV spectroscopic AUC approach for the measurement of ibuprofen.

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