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Review Article

UV Spectrophotometric Evaluation of Drug Solubility Profiles in Varied Pharmaceutical Formulations

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ABSTRACT

This study aimed to develop a method for comparing the solubility profiles of three distinct brands of Diclofenac Sodium formulations using UV spectrophotometry. The analysis was conducted under optimal dissolution conditions, employing 900 mL of pH 7.4 phosphate buffer as the dissolution medium, with a paddle apparatus (Type II) set to 100 revolutions per minute. A wavelength of 282.2 nm was used for the UV spectrophotometric measurement of drug release. The proposed method demonstrated a drug release percentage close to 100%, aligning well with the labeled claims of the marketed tablet formulations. This approach provides a simple, precise, and reliable technique for comparative analysis of solubility profiles across various formulations, supporting pharmaceutical quality control and formulation optimization.

Keywords: Diclofenac Sodium, UV Spectrophotometry, Solubility Profiles, Formulation Comparison, Dissolution Medium

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1. Introduction

To have the desired impact, medications must be high-quality, safe, and effective. Establishing capable national drug regulatory agencies with the manpower and other resources needed to regulate the production, importation, distribution, and sale of pharmaceuticals is essential to ensuring these qualities. Delivering a therapeutic dose of the medication to the right location in the body and keeping the plasma concentration at that level for a set amount of time are essential components of any drug delivery system. A medication's quality plays a significant role in guaranteeing a patient's health and well-being [1].

Dysmenorrhea.1 A nation's mortality and morbidity rate rises when its pharmaceuticals are of worse quality. This project's goal is to assess the quality of drugs that are sold in India and used to treat rheumatoid arthritis, degenerative joint disease, ankylosing spondylitis, and related conditions. It also aims to treat pain from minor surgeries, trauma, and dysmenorrhea [2].

Because of their exceptional analgesic, antiphlogistic, and antipyretic properties, non-steroidal anti-inflammatory medicines (NSAIDs) are among the most often prescribed medications. The only non-steroidal anti-inflammatory medications used between 1875 and 1940 were derivatives of salicylic acid. In the last forty years, there has been a sharp rise in the quantity of new medications and NSAID sales [3].

The most often prescribed NSAID in the world for the treatment of pain and inflammation in a variety of conditions, such as osteoarthritis and rheumatoid arthritis, is diclofenac sodium (DFS) [4]. However, following oral administration, prolonged use of this medication results in several detrimental side effects, including poor absorption pattern, low effectiveness, gastrointestinal bleeding, gastrointestinal ulcers, and poor patient compliance. Consequently, to prevent complications associated with oral administration, a different method of administering DFS is required. NSAIDs that inhibit both COX-1 and COX-2 enzymes include diclofenac. Prostanoids (i.e., prostaglandin [PG]-E2, PGD2, PGF2, prostacyclin [PGI2], and thromboxane [TX] A2) are not synthesized when NSAIDs bind to COX isozymes. The primary mechanism of NSAIDs' strong analgesic and anti-inflammatory effects is thought to be their suppression of PGE2, the predominant prostanoids generated in inflammation [5-6].

In the field of therapeutics, combination medication products have a longstanding and significant significance. Rationally designed fixed-combination medications can offer increased affordability, increased convenience, and occasionally increased safety and efficacy [7]. UV spectrophotometric methods are mostly employed in multicomponent analysis, which minimizes the laborious process of separating interferents and permits the measurement of an increasing number of analytes, ultimately cutting down on the amount of time and money required for analysis Several sophisticated, fast, selective, and very accurate instrumental procedures have been described in the last several decades. The most significant of them is spectrophotometry, which is used to a wide range of materials. Modern analytical chemists found this approach beneficial because to its high accuracy, precision, sensitivity, and ease of access to spectrophotometers [8].

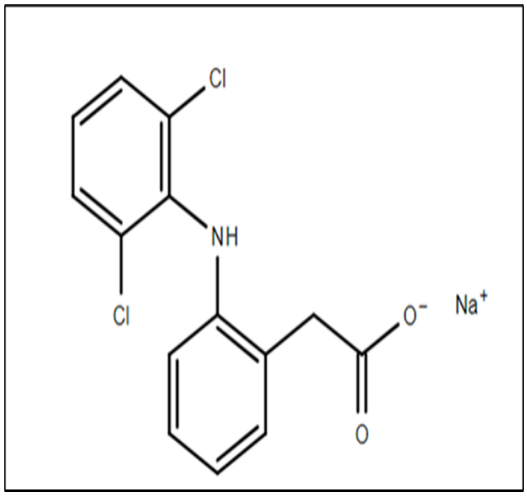

Fig.1: Structure of Diclofenac Sodium

2. Methods and Materials

2.1. Chemicals and Reagents

Diclofenac Sodium API was obtained from Alkem Labs Ltd., Nagpur, India. Commercially available tablets, including Reactin® (5 mg), Voveran® (5 mg), and Fenac® (5 mg), were purchased from the local pharmaceutical market. All chemicals, reagents, and solvents used in this study were of analytical reagent grade. Solutions were prepared using double-distilled water to ensure precision and consistency.

2.2. Instruments

All spectrophotometric measurements were carried out using a Jasco UV-Vis Spectrophotometer (V-630 Series). The dissolution tests were conducted using an Electrolab Tablet Dissolution Tester (TDT-06P), which allowed precise monitoring of drug release profiles.

2.3. Preparation of Standard Stock Solution

A standard stock solution was prepared by accurately weighing 10 mg of Diclofenac Sodium and dissolving it in a 100 mL volumetric flask containing phosphate buffer solution (pH 7.4). The solution was further diluted to 10 mL to achieve the desired concentration. Aliquots of 0.5, 1.0, 1.5, and 2.0 mL were then diluted with phosphate buffer solution to obtain a series of standard solutions for calibration [1].

2.4. Working Standard Solution

A working standard solution with a concentration of 100 µg/mL was prepared by diluting 1.0 mL of the stock solution with phosphate buffer solution to a final volume of 10.0 mL.

2.5. Preparation of Sample Solution

Dissolution studies were conducted by filling six vessels of the dissolution tester with 900 mL of phosphate buffer solution (pH 7.4), maintained at a temperature of 37 ± 0.5°C. Individual Diclofenac tablets were accurately weighed and introduced into the dissolution baskets. The distance between the basket and the bottom of the vessel was set to 25 ± 2 mm. The apparatus was operated at a specific rotation speed for 45 minutes. At predetermined intervals, 25 mL samples were collected, filtered, and diluted to 10 mL. Absorbance was measured at 276 nm using the UV spectrophotometer, and the drug concentration was determined using the calibration curve. The dissolution process was monitored for up to one hour to simulate the drug release in vitro [2,3].

3. Result and Discussion

3.1. UV-visible spectrophotometric analysis

For the selection of analytical wavelength Diclofenac sodium (10 µg/mL) in buffer solutions such as phosphate buffer solution were prepared and scanned in the range of 200-400 nm in 1.0 cm cell against solvent blank (buffer solution). Diclofenac sodium shows maximum absorbance at 282.2 nm in phosphate buffer. Therefore 282.2 nm was considered as λmax for further experimentation which was shown in Fig.2

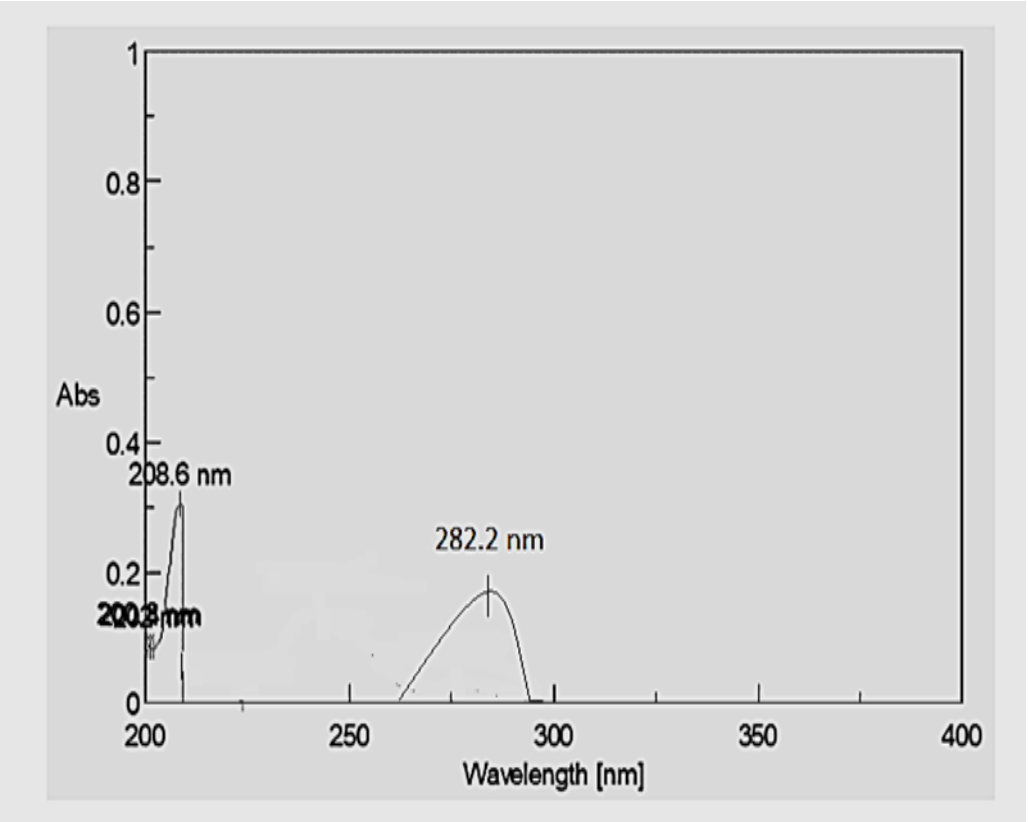

Fig.2: Spectra of Diclofenac Sodium

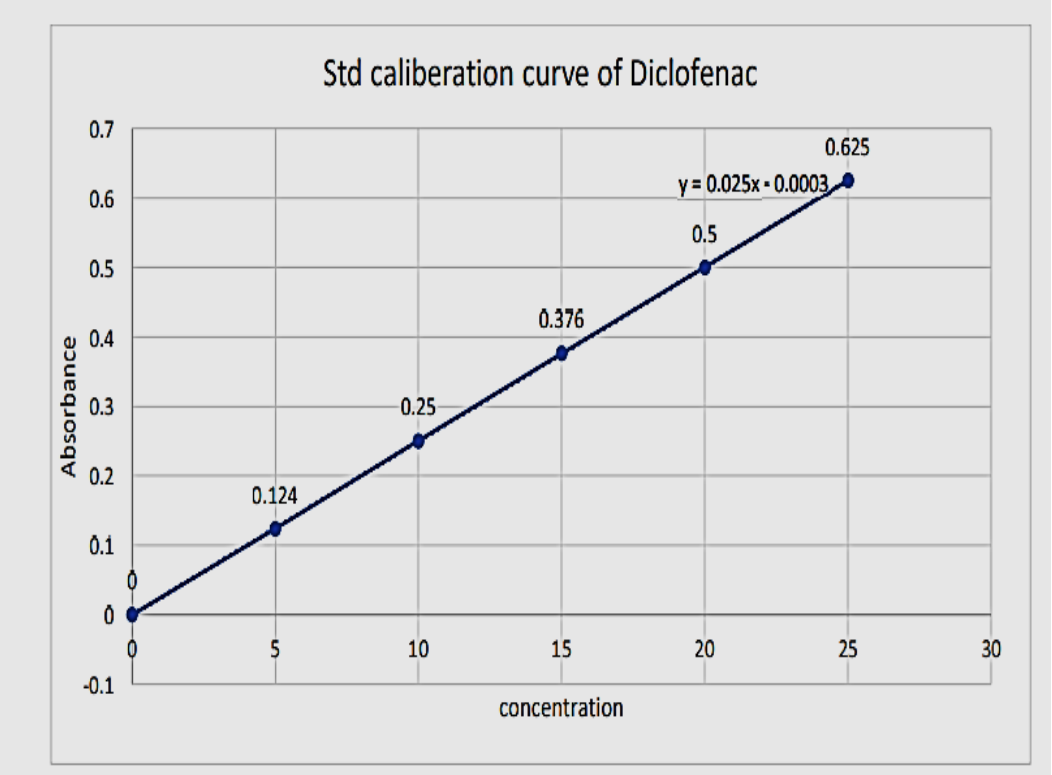

Fig.3: Standard Calibration curve of Diclofenac

Table 1: Standard Calibration Absorbance of Diclofenac

Concentration	Absorbance
0	0
1	0.124
2	0.250
3	0.376
4	0.500
5	0.625

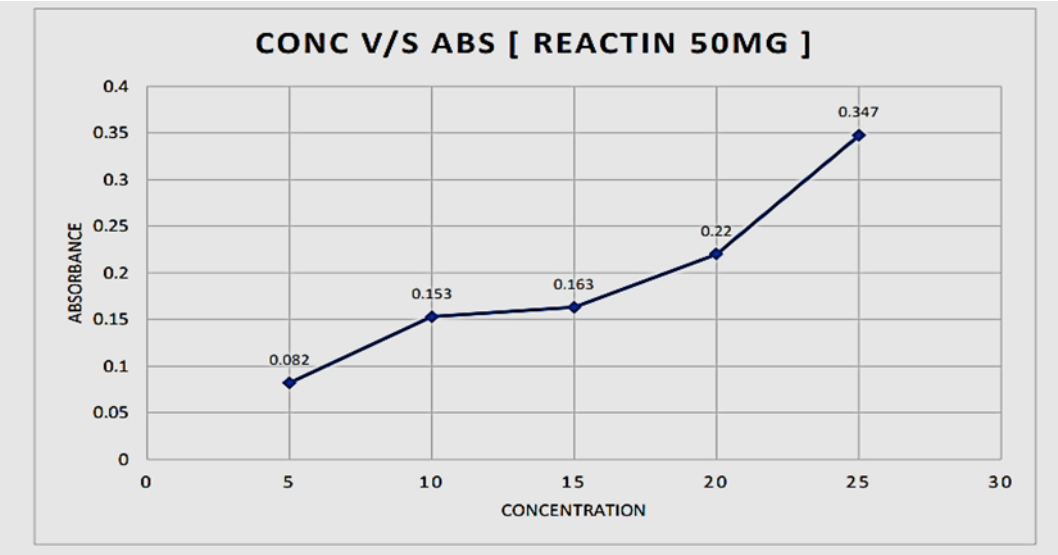

Fig.4: Absorbance curve of Reactin

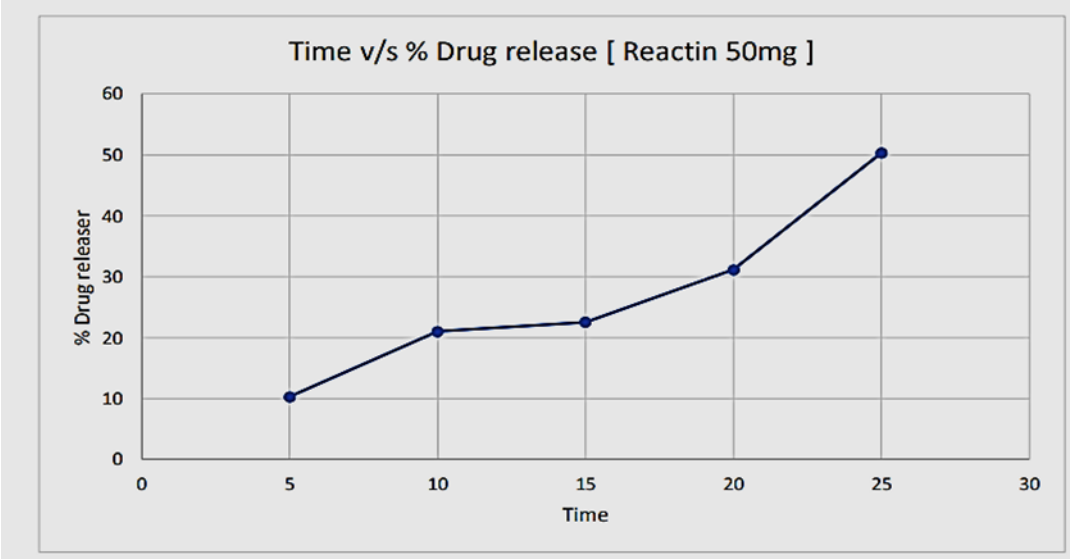

Fig.5: Time v/s % Drug release curve of Reactin

Table 2: % drug release of Reactin marketed brand

Time	Absorbance	Concentration	Dilution factor	Conc in (µg)	Conc in (mg)	% drug release
5	0.082	5	10	5.7226	5.150	10.30%
10	0.153	10	10	11.6890	10.520	21.04%
15	0.163	15	10	12.5294	11.276	22.55%
20	0.220	20	10	17.3193	15.587	31.17%
25	0.347	25	10	27.9916	25.192	50.38%

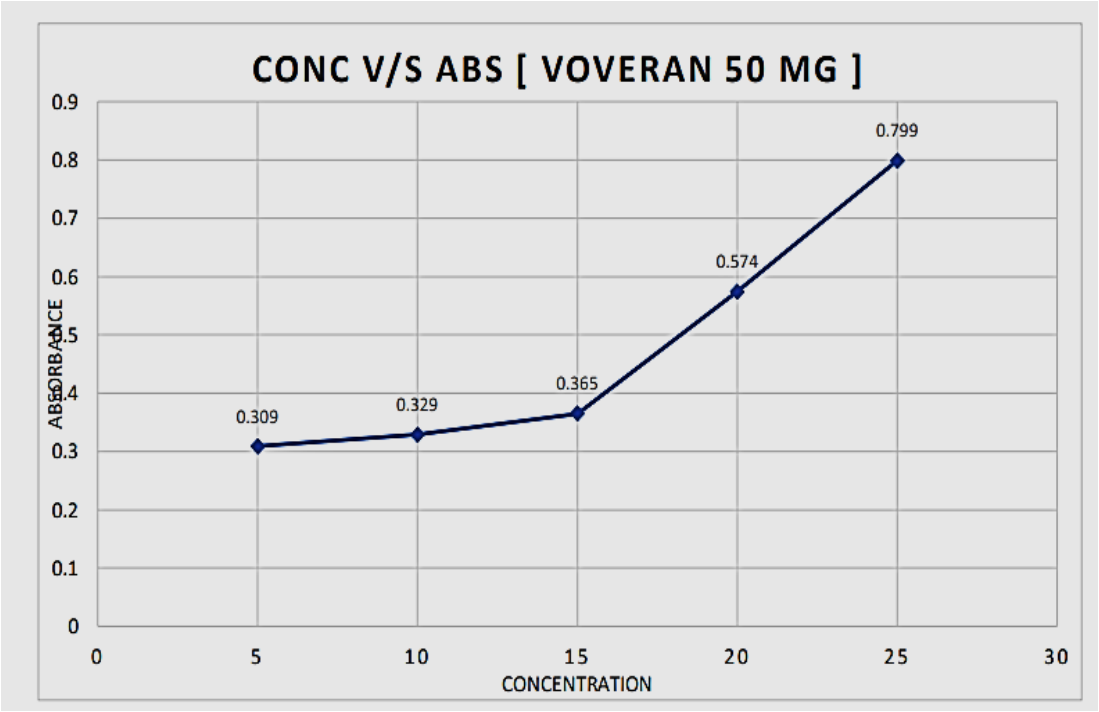

Fig. 6: Absorbance curve of Voveran

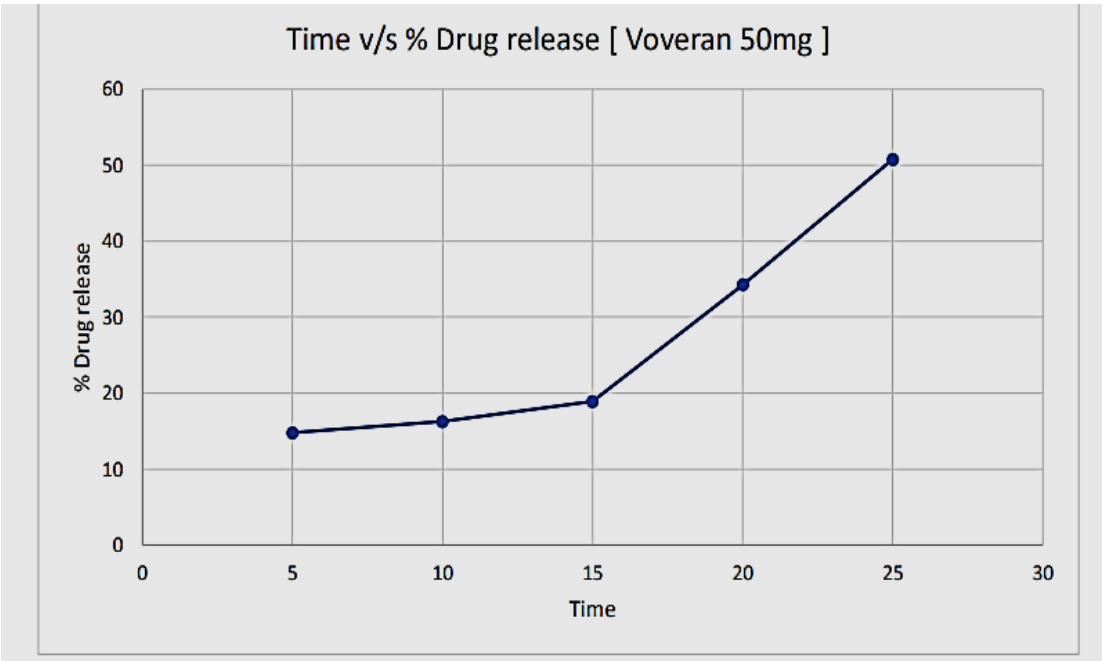

Fig.7: Time v/s % Drug release curve of Voveran

Table 3: % drug release of Voveran marketed brand

Time	Absorbance	Concentration	Dilution factor	Conc in (µg)	Conc in (mg)	% drug release
5	0.309	5	10	8.2163	7.394	14.78%
10	0.329	10	10	9.0326	8.129	16.25%
15	0.365	15	10	10.5020	9.451	18.90%
20	0.574	20	10	19.0326	17.129	34.25%
25	0.799	25	10	28.2163	25.394	50.78%

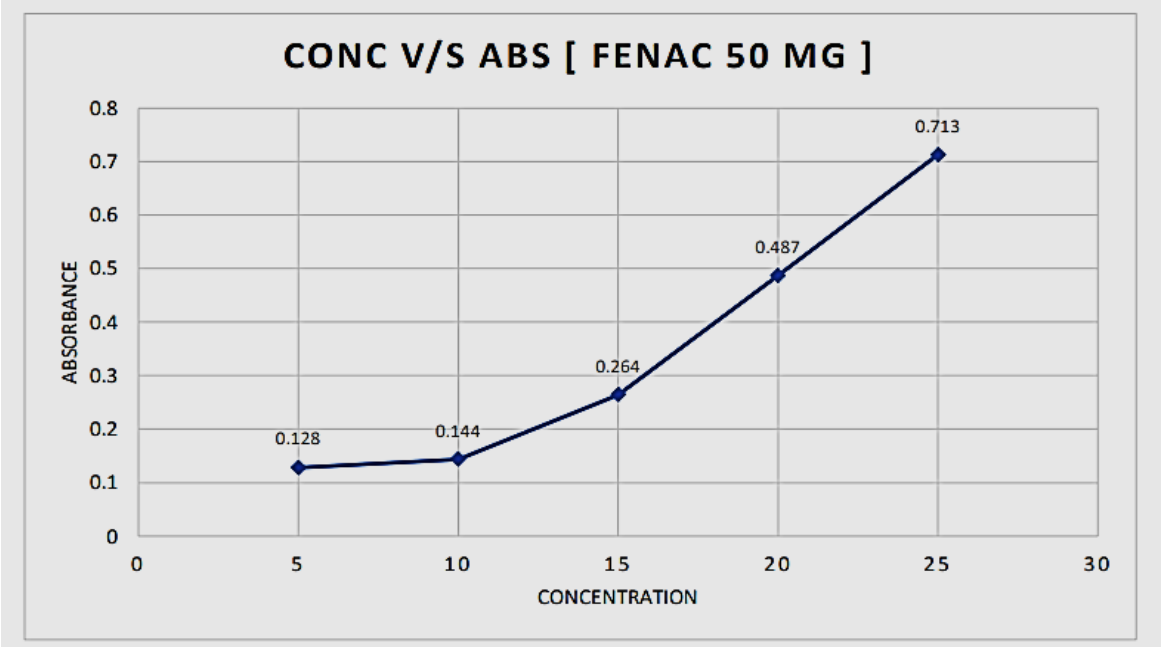

Fig.8: Absorbance curve of Fenac

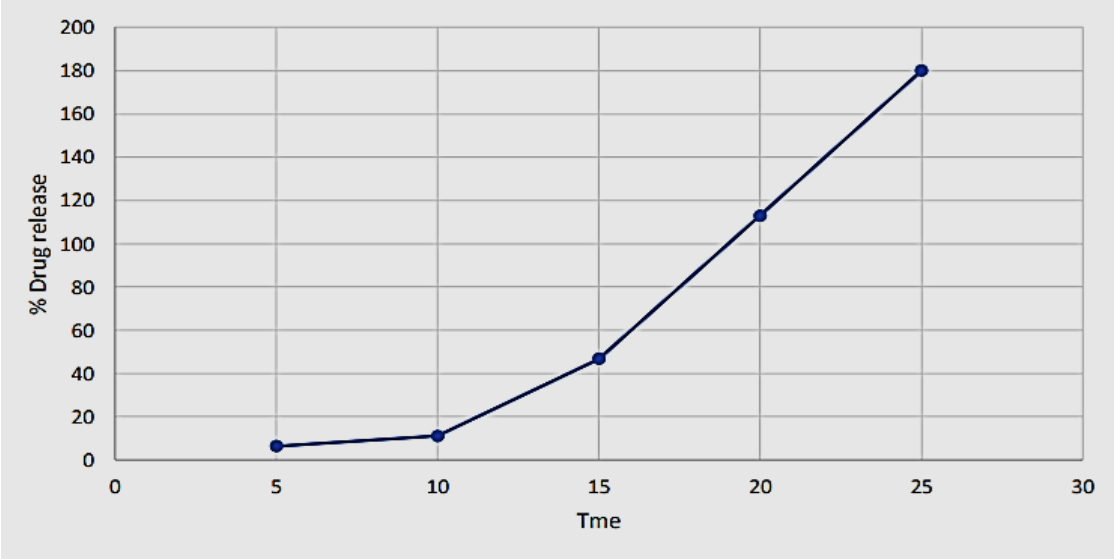

Fig.9: Time v/s % Drug release curve of Fenac

Table 4: % drug release of Fenac marketed brand

Time	Absorbance	Concentration	Dilution factor	Conc in (µg)	Conc in (mg)	% drug release
5	0.128	5	10	0.7029	0.632	6.32%
10	0.144	10	10	1.2310	1.107	11.07%
15	0.264	15	10	5.1914	4.672	46.72%
20	0.487	20	10	12.5511	11.296	112.9%
25	0.713	25	10	20.0099	18.008	180%

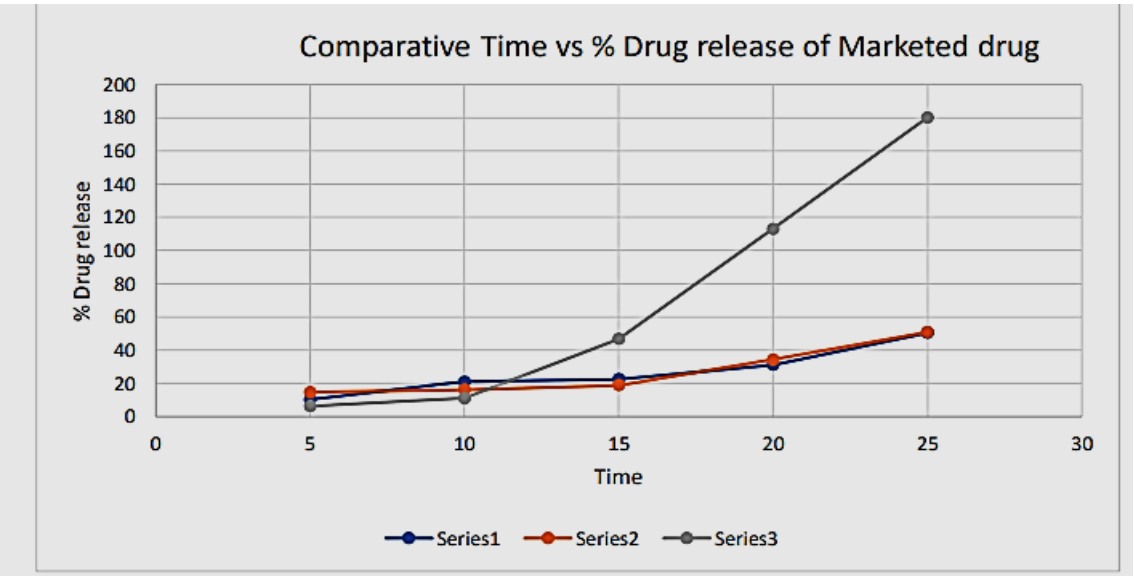

Fig.10: Comparative Time v/s Drug release curve of Marketed brands

Table 5: Comparative % drug release of all three marketed brands

Time	Reactin % Drug Release	Voveran % Drug Release	Fenac % Drug Release
5	10.30%	14.78%	6.32%
10	21.04%	16.25%	11.07%
15	22.55%	18.90%	46.72%
20	31.17%	34.25%	112.9%
25	50.38%	50.78%	180%

Pharmacopoeias state that at least 75% of the prescribed dosage of diclofenac should dissolve in 40 minutes, yet the data only indicate that one sample dissolves at a rate higher than 75%.For tablets to be absorbed in the gastrointestinal system, they must dissolve. There won't be any absorption if pills don't dissolve. The remaining two brands passed the disintegration test, with two brands' samples falling short of 75%.

Discussion

Effective regulatory oversight within the pharmaceutical industry plays a pivotal role in improving product quality, reducing manufacturing time, and minimizing costs. Among various quality parameters, dissolution was identified as a critical factor where inconsistencies between brands were evident. In this study, only two of the three tested brands met the dissolution criteria when analyzed via UV spectrophotometry. One brand exhibited significantly slower dissolution rates, indicating substandard tablet quality.

The results highlight disparities in the quality of pharmaceuticals produced by different manufacturers. While some brands conform to established standards, others fail to meet basic quality benchmarks, potentially compromising therapeutic efficacy. These findings emphasize the need for stricter regulatory measures to address the production and marketing of substandard drugs. Regulatory bodies should implement new policies to prevent adulteration and ensure that all pharmaceutical products meet prescribed quality standards.

Regulators must extend their jurisdiction to encompass all aspects of drug manufacturing and distribution, particularly ensuring compliance with Good Manufacturing Practices (GMP). Additionally, strict enforcement of labeling requirements and certification of analysis for pharmaceutical shipments, both domestically and internationally, is essential. APIs and raw materials used in drug formulations should be explicitly labeled as "For Pharmaceutical Use" or represented with standardized pictograms.

Establishing multidisciplinary teams within regulatory agencies to address illegal activities promptly and professionally is crucial. Enhanced collaboration with international law enforcement organizations, including customs and criminal investigation offices, is also vital. Monitoring free trade zones and enforcing compliance within these regions can significantly reduce the circulation of inferior pharmaceutical products.

Conclusion

This study successfully developed and validated a UV-spectrophotometric method for the determination of Diclofenac Sodium, utilizing a calibration curve approach. The dissolution test results demonstrated the method’s accuracy and

reliability. Upon comparing the dissolution rates of Reactin, Voveran, and Fenac, it was found that the dissolution percentages were 31.17%, 34.25%, and 112.9%, respectively. According to pharmacopoeial standards, a minimum of 75% of the labeled dose of Diclofenac Sodium should dissolve within 40 minutes. However, the data revealed that only one brand (Fenac) exceeded the 75% dissolution threshold, while the other two brands failed to meet the requirement.

The inability of the two brands to meet the dissolution criteria indicates potential issues with their formulation, which could impair gastrointestinal absorption and, consequently, therapeutic efficacy. These findings underscore the importance of rigorous quality control in pharmaceutical manufacturing to ensure drug safety and efficacy.

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Conflict of Interest

The authors declare no conflicts of interest regarding the publication of this research.

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