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Research Article

Comparative Assessment of Drug Solubility Profiles in Various Formulations Using UV Spectrophotometry: A Comprehensive Study

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ARTICLEINFO

ABSTRACT

This study aimed to establish a technique for comparing the solubility profiles of three distinct brands of Diclofenac Sodium medication formulations using UV Spectrophotometry. Diclofenac Sodium was analyzed using a precise UV spectrophotometric method under optimal dissolution conditions, employing 900 milliliters of pH 7.4 phosphate buffer as the dissolution medium and a paddle (type II) apparatus stirring at 100 revolutions per minute. A detecting wavelength of 282.2 nm was utilized for UV spectrophotometric assessment of drug release. The proposed method demonstrated an anticipated drug release percentage close to 100%, which correlated well with the labeled claim of marketed tablet formulations. This approach offers a straightforward, accurate, and reliable means for comparative analysis of drug solubility profiles in various formulations, aiding in pharmaceutical quality assessment 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].

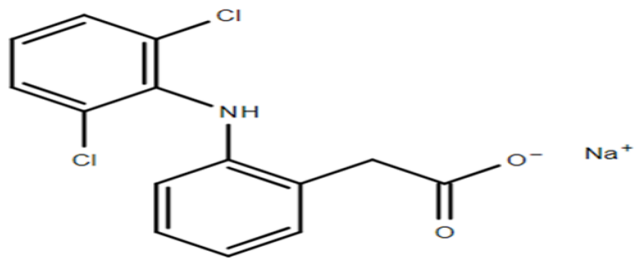

Fig.1: Structure of Diclofenac Sodium

2. Method and Materials

2.1. Chemicals and Reagents

Diclofenac API samples were sourced from Alkem Labs Ltd, Nagpur, India, while tablets containing the drug (Reactin® 5mg, Voveran® 5mg, Fenac® 5mg) were procured from the local market. All solvents, materials, and reagents used in the Diclofenac assay were of analytical reagent grade and prepared using double distilled water.

2.2. Instruments

Spectral measurements were conducted using the Jasco-UV module version V-630 series prominence JASCO UV spectrophotometer. Dissolution testing was performed using the Electrola-Tablet Dissolution tester-TDT-06P.

2.3. Preparation of Standard Stock Solution

To establish a standard calibration curve, 10 mg of Diclofenac sodium was accurately weighed and placed in a 100 ml volumetric flask. The volume was adjusted to 10.0 ml with phosphate buffer solution pH 7.4. From this stock solution, aliquots of 0, 0.5, 1.0, 1.5, and 2.0 ml were taken and made up to 10 ml with phosphate buffer solution, creating a series of standard solutions [9].

2.4. Working Standard Solution

A working standard solution was prepared by diluting 1.0 mL of the standard stock solution to 10.0 mL, resulting in a concentration of 100 µg/mL of Diclofenac Sodium.

2.5. Preparation of Sample Solution

Each of the six dissolution vessels was filled with 900 ml of distilled water and maintained at a temperature of 37°C (±0.5). Diclofenac tablets were weighed and transferred into each vessel's baskets, ensuring a distance of 25±2 mm between the basket and the vessel bottom. The apparatus was operated at specified rpm, and after 45 minutes, 25 ml samples were withdrawn from each vessel, filtered, and diluted to 10 ml. The absorbance of these solutions was measured at 276 nm using a UV-visible spectrophotometer, and drug concentration was calculated using the calibration curve. The dissolution study was continued for 1 hour to simulate the drug release in vitro [10,11].

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

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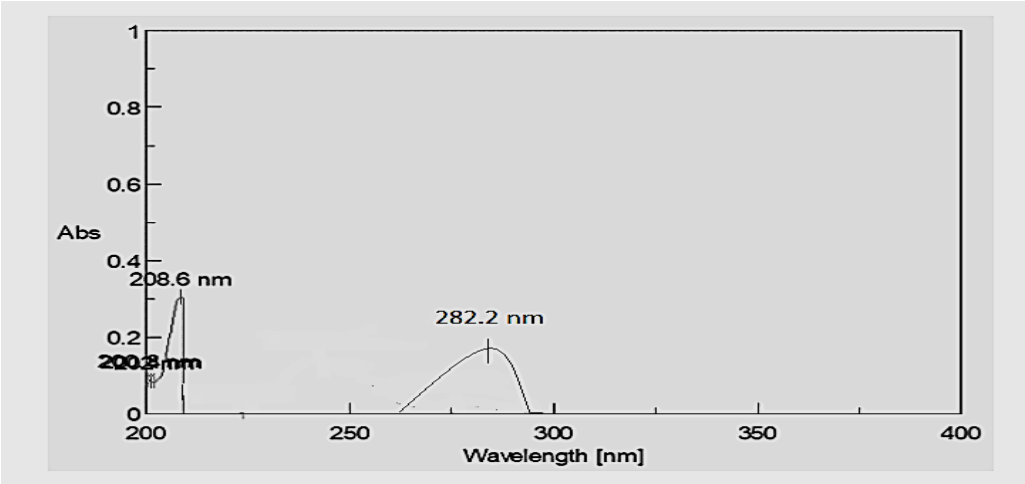

Fig.2: Spectra of Diclofenac Sodium

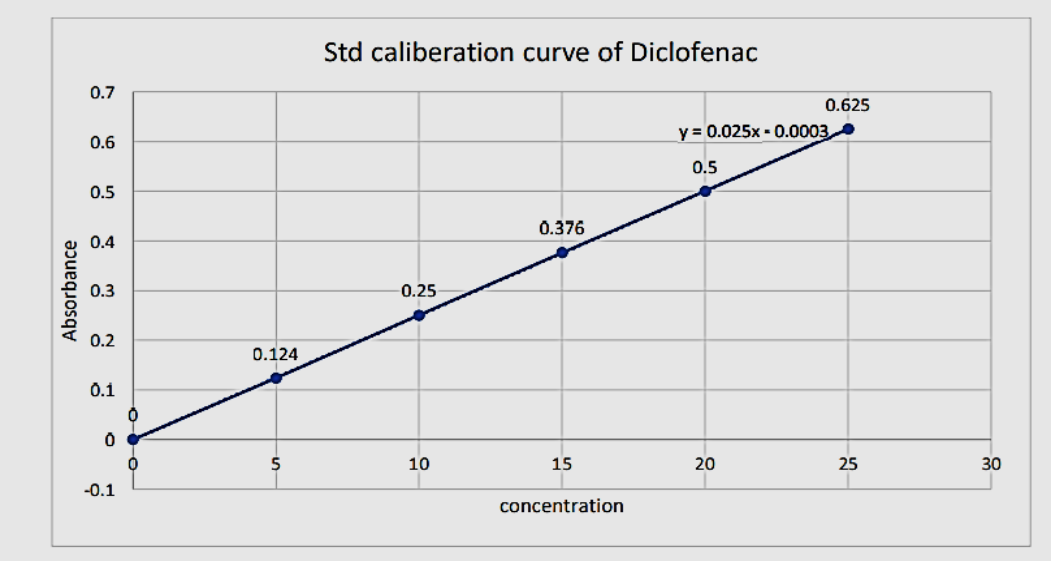

Fig.3: Standard Calibration curve of Diclofenac

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

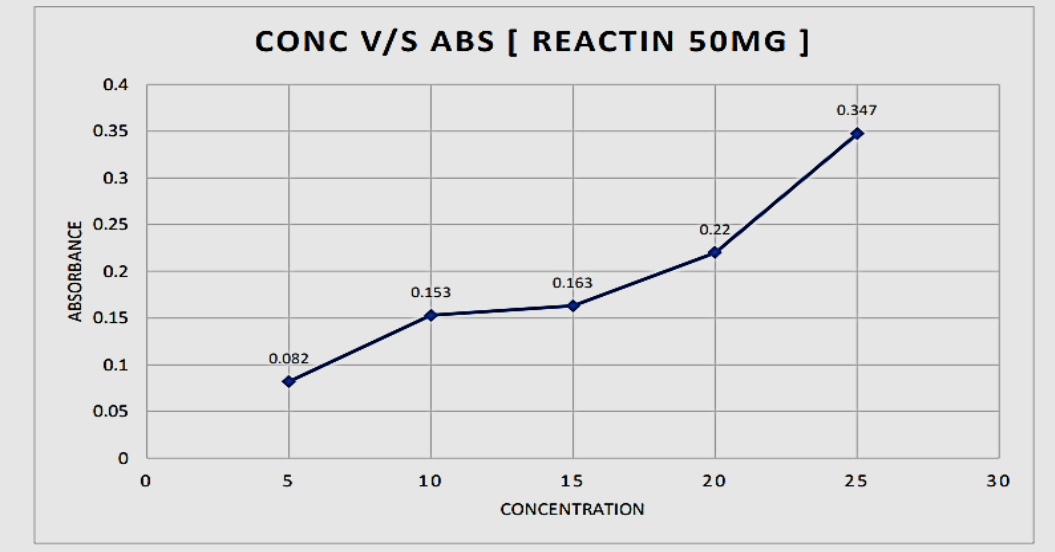

Fig.4: Absorbance curve of Reactin

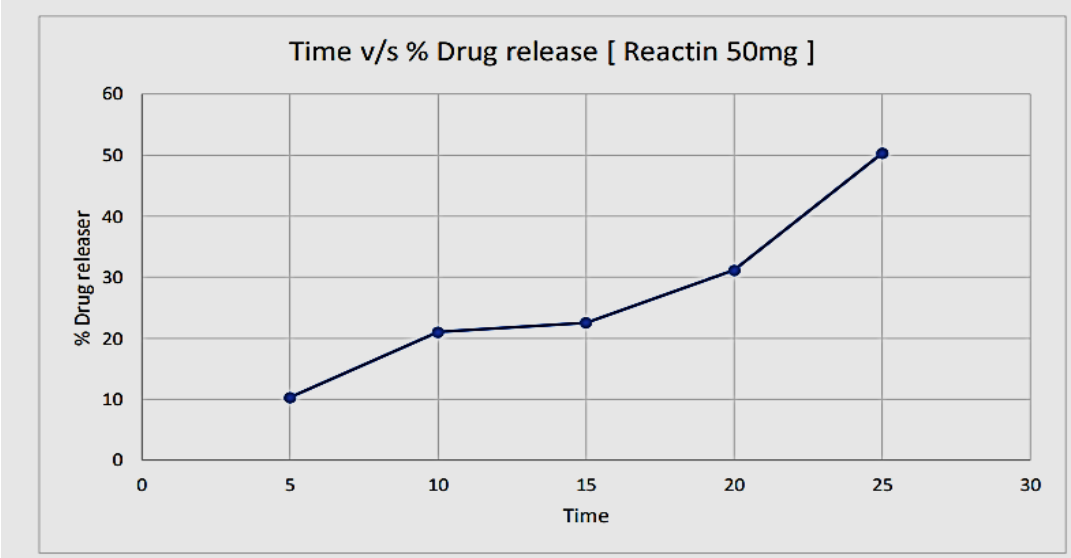

Fig.5: Time v/s % Drug release curve of Reactin

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%

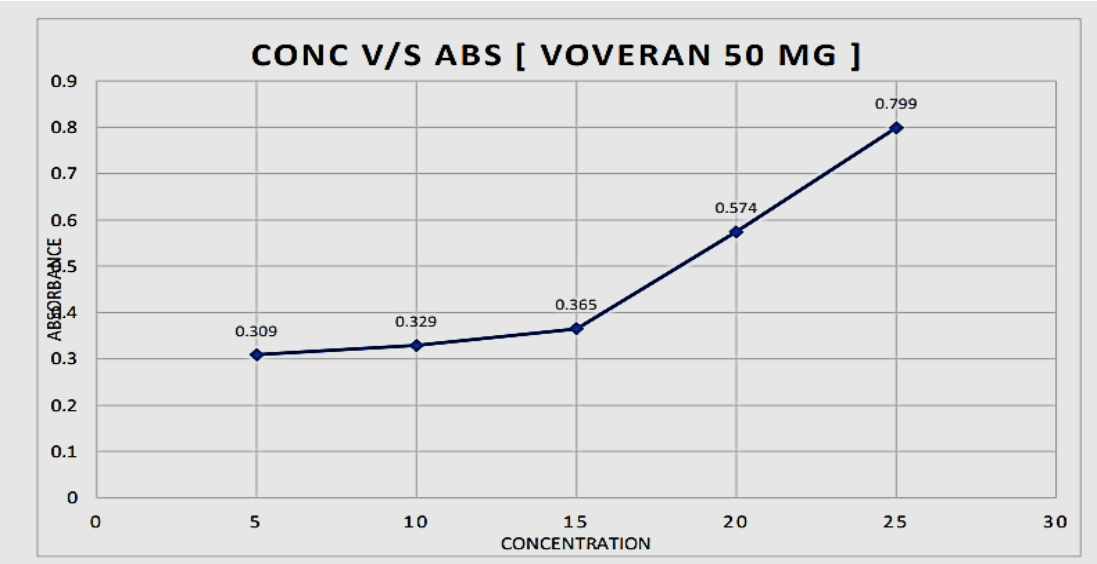

Fig. 6: Absorbance curve of Voveran

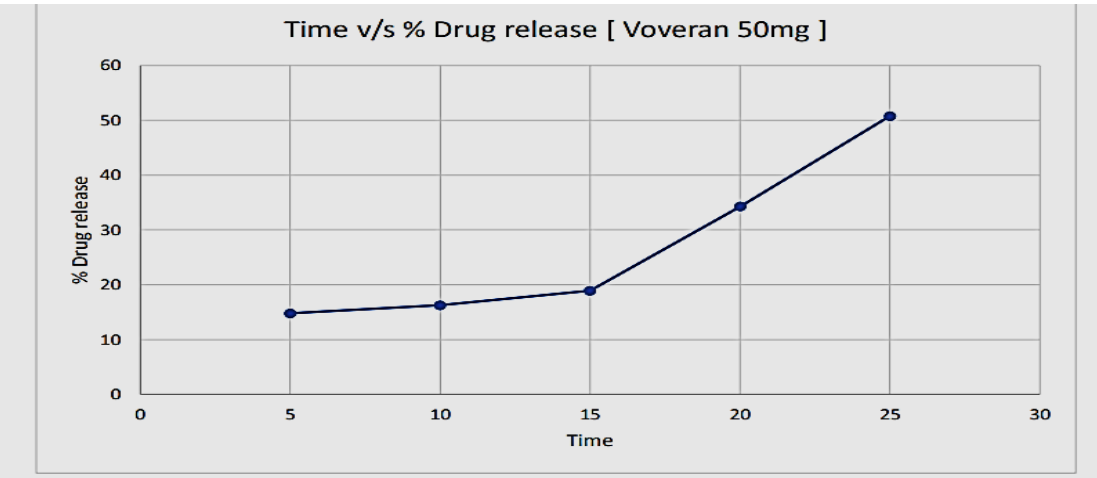

Fig.7: Time v/s % Drug release curve of Voveran

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%

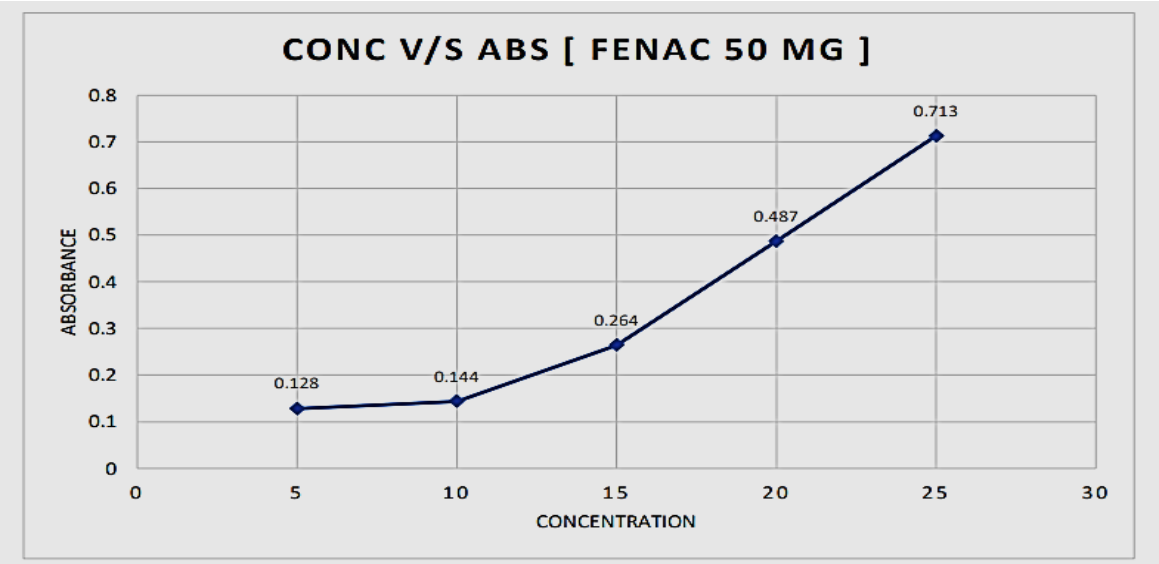

Fig.8: Absorbance curve of Fenac

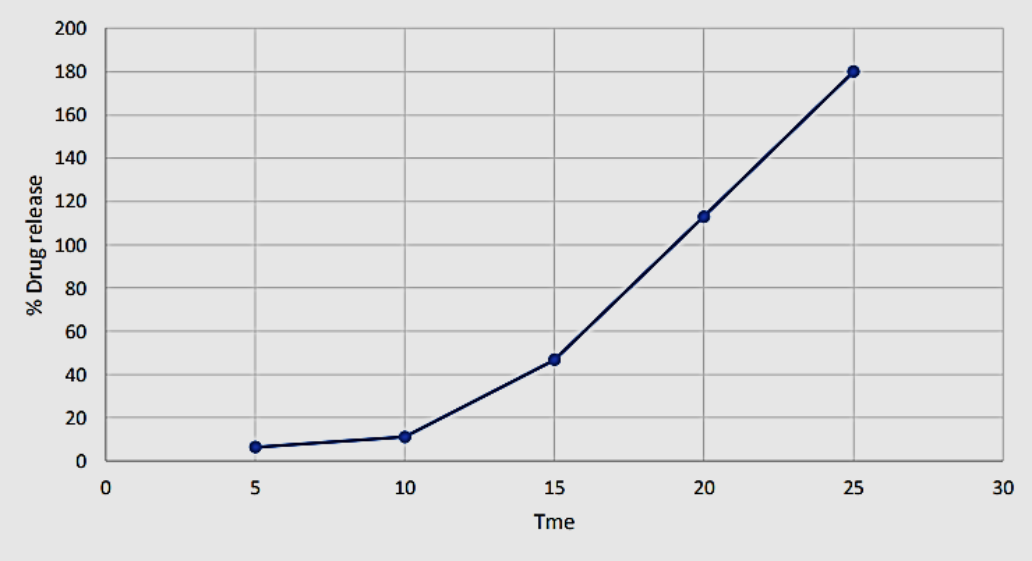

Fig.9: Time v/s % Drug release curve of Fenac.

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%

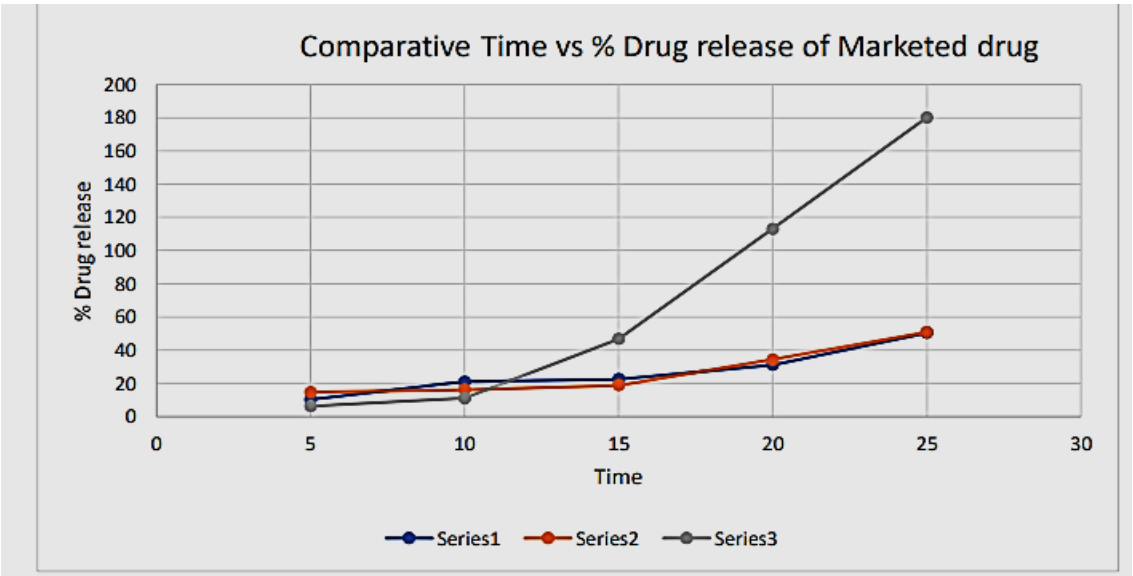

Fig.10: Comparative Time v/s Drug release curve of Marketed brands

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

Vigilant oversight of various processes within the pharmaceutical industry can lead to decreased manufacturing time and expenses while also enhancing product quality. Dissolution was discovered to be the crucial factor at which issues between various brands arise. Just two brands were able to pass the UV Spectrophotometry-analysed dissolving test. One sample breaks down much more slowly than the others, indicating that the tablet is not up to par. We may infer from the experiment that although some firms give standard pharmaceuticals, others provide subpar drugs. To prevent adulteration and regulate inferior pharmaceuticals, the drug administration should create new policies and drug statutes. Extend their regulatory jurisdiction to include makers of pharmaceutical products that are marketed, especially with regard to inspecting GMP compliance. They should also enforce strict guidelines for labeling and certificates of analysis for shipments that are being transported internationally. Enact laws mandating that APIs and any other raw materials used in the preparation of pharmaceuticals bear the label "for pharmaceutical use" or be appropriately represented by a pictogram. Form a multidisciplinary team inside the regulatory body to look into illegal activity as soon as possible and in a professional manner. Keep an eye on free ports and improve cooperation with national and international law enforcement organizations, such as customs officers and criminal investigation offices.

4. Conclusion

Based on the calibration curve approach, the UV-Spectrophotometric method was created to determine Diclofenac Sodium. The dissolving test comparing findings produced by the UV technique were exact, accurate, and dependable. After comparing the medication release for Reactin, Voveran, and Fenac it was discovered to be 31.17%, 34.25% and 112.9% respectively. 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 tablets don't dissolve. The samples of two brands were below 75%, while the remaining two brands passed the dissolving test.

Acknowledgement

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Conflict of Interest

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

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