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Original Research Article

A Comparative Study of Dissolution Profiles on Various Brands of Diclofenac Sodium Prolonged Release Tablet Formulation

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ABSTRACT

This study aims to analyse and compare the disintegrating patterns of prolonged-release tablets of diclofenac sodium purchased from a variety of brands that are commercially available on the Indian national market. Each formulation contains the same quantity of the active pharmaceutical ingredient, but the excipients used may be of a different type or in a different proportion than those used in the other formulations. On the dissolution apparatus, using the same dissolution medium with a pH of 7.5, the effect of these formulation variations on the in vitro release qualities of the various dosage forms was compared. During the course of this investigation, it was discovered that branded formulations offered for sale by well-known pharmaceutical companies demonstrate USP-compliant release. On the other hand, formulations manufactured by local firms do not conform to the standards' requirements.

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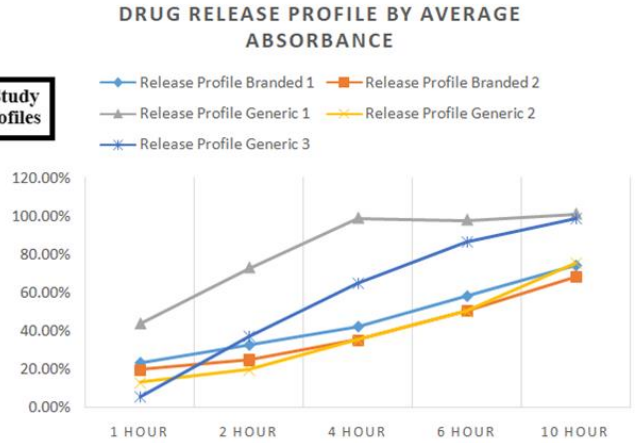
GRAPHICAL ABSTRACT

Various Brands of Diclofenac Sodium Prolonged Release Tablet Formulation

A Comparative Study of Dissolution Profiles



1. INTRODUCTION

Oral solid dosage forms are the formulations that are employed the most frequently for both newly developed and already existing medications with a sustained release, and they are also the administration method preferred for many different drugs [1]. Prolonged-release systems have numerous clinical benefits, such as decreased dose frequency, which improves patient compliance; fewer variations in medication plasma concentrations, which results in a lower incidence of adverse effects; and maybe greater efficacy. Diclofenac sodium is a powerful non-steroidal anti-inflammatory medication (NSAID) that also has antipyretic and analgesic effects [2]. Rheumatoid arthritis, osteoarthritis, and akylosing spondylitis are examples of degenerative joint illnesses that can be treated with this medication over the course of a patient's lifetime. The physicochemical action on the stomach mucosa and the inflammatory action on both the small bowel and the colon cause it to have a rather high incidence of gastrointestinal side effects. This is due to the fact that both of these actions are inflammatory in nature. Because of these negative effects and the fact that diclofenac sodium has a very short biological half-life, it makes an excellent choice for delayed-release formulations. Diclofenac sodium has weakly acidic characteristics (pKa is around 4), and the pH of the medium determines whether or not it is soluble. It has a low solubility in water, a very low solubility in phosphate buffer with a pH of 6.8, and a practically insoluble solubility in hydrochloric acid with a pH of 1.1. According to the Biopharmaceutical Classification System (BCS), this substance can be placed in the Class II category of pharmaceuticals [3, 4]. The BCS is a scientific framework for classifying drug substances based on their aqueous solubility and intestinal permeability. These are the primary parameters that influence the rate and extent of absorption of a drug substance through gastrointestinal membranes and have a significant influence on the substance's bioavailability [5]. The British Chemical Society was responsible for developing the BCS. Class II medications are those that have a high permeability but whose solubility in aqueous media is not sufficient for the entire dose to be dissolved in the gastrointestinal tract [6]. This definition is applied to drugs with high permeability.

Therefore, the rate-limiting phase in the process of absorption for these compounds is the dissolution step. Because the choice of medium for in vitro dissolution tests can depend on a wide variety of factors, including pH, ionic strength, buffer capacity, presence of surfactants, agitation, and medium volume, it is expected that

the choice of medium will play a very important role in the dissolution of Class II drugs [7]. This is because the choice of medium is expected to play a very important role in the dissolution of Class II drugs. Drug substances and excipients are the two components that make up a pharmaceutical product. The proportion between them, the type of Excipients, and the production process of the final product are all decided depending on the content, physicochemical, and bulk properties of the medicine, as well as the features of its absorption [8]. When everything is considered together, this gives each product its own unique dissolving properties. During the various stages of the development of a new drug product, the quality of a dosage form is continuously improved, and a dissolving test is a dependable instrument for evaluating formulation and processing variables that may influence the bioavailability of the medication [9]. To comply with requirements imposed by the European Union, controlled-release formulations must initially undergo an in vitro test to determine their release rate. This test must involve a dissolution study conducted in various settings. The testing condition that has the highest discriminatory power should be chosen for routine control of scale-up and production batches. This will assure both consistency from batch to batch as well as that the dissolution profiles will stay identical to those of pivotal clinical batches. In addition, a test for dissolution can be utilised to establish the bioequivalence of a product that is substantially identical to another [10]. The dissolution test for immediate or controlled release in solid oral dosage forms, including tablet, suspensions, chewing gum, transdermal patches, implants, and others, has recently been expanded. The factors that follow must be carefully taken into account when developing the test technique because to the various characteristics of early dosage forms, site absorption, and dosing routes and applications: apparatus choice, dissolve medium, agitation, and temperature [11].

The method validation is necessary to assess the reproducibility test since the dissolution experiments are used to imitate the in vitro behaviour of the pharmaceutical dosage form. These traits will make it easier to forecast *in vitro* performance. Few papers have been published about dissolution tests for dosage form, which indicates that further information about pharmaceutical dosage forms is required. Although there are several elements, such as physical parameters (particle size) and formulation features, that affect the medication dissolving rate, the suspensions are dispersion systems. Because of their acceptability and convenience of administration, they are chosen by the elderly and paediatric populations [12].

This study's objective is to assess and compare the dissolving characteristics of various brands of diclofenac sodium prolonged release tablets that were bought from local pharmacy stores [13]. The same experimental conditions will be used for all of the experiments. Depending on the formulation, excipients such diluents, disintegrants, lubricants, binders, and surfactants may vary in type and/or quantity. The amount of the active medicinal substance is the same in every formulation, though. The release properties of the various dosage forms may be impacted by these formulation changes, which might possibly affect the drug's bioavailability and raise questions about the interchangeability of the products [14].

2. EXPERIMENTAL

2.1. Materials

A retail pharmacy in Nashik, Maharashtra, India, was visited to acquire various brands of diclofenac sodium with a label strength of one hundred milligrammes. Every test was carried out before the products' respective expiration dates. The powdered form of diclofenac sodium

was a present from the Research Lab Fine Chem Industries located in Mumbai 400002 (India). Sodium phosphate dibasic, phosphoric acid (provided by Research-Lab Fine Chem Industries, Mumbai 400002, India), and deionized water were the reagents utilised in this experiment. Each chemical that was used was of analytical grade. Throughout the process entirety, distilled water was used.

Buffer Preparation (Phosphate Buffer Solution, pH 7.5, 0.05 M)

Dissolve 0.89 g of sodium phosphate dibasic in about 80 ml of water. Adjust the pH to 7.5 with an 8.5 percent V/V solution of phosphoric acid and dilute to 100.0 ml with water [15].

2.2. Standard preparation

Weigh accurately 10 mg of diclofenac sodium powder and dissolve it in 100 ml of phosphate buffer solution, pH 7.5, 0.05 M (solution A). From solution A, pipette out 1 ml into a 10 ml volumetric flask and dilute to mark with Phosphate Buffer Solution pH 7.5, 0.05 M (solution B) [16].

2.3. Instrumentation

Vinsyst Technologies' Model No. VDS6 USP Type 2 Dissolution Apparatus is a piece of equipment used for dissolution research. Spectrophotometer with a UV-Visible double beam and matching quartz cells (1 cm) The Shimadzu UV-1800 was the instrument of choice for the comparative analysis of dissolution profiles.

2.4. Dissolution Procedure

After assembling the apparatus, bringing the dissolution medium to equilibrium at 37 0.5 °C, and then removing the thermometer, place the stated volume of the dissolution medium (1%) in the vessel of the specified apparatus supplied in the particular monograph. After inserting one dosage unit into the apparatus while taking precautions to prevent air bubbles from forming on the surface of the dosage unit, immediately begin operating the apparatus at the rate prescribed in the specific monograph.

Within the time interval that has been specified, or at each of the times that have been stated, a specimen is to be removed from a region that is halfway between the surface of the dissolution medium and the top of the rotating paddle, and it must be no more than one centimetre from the wall of the vessel. Carry out the analysis in accordance with the guidelines provided in the specific monograph, utilising an appropriate test procedure. It is recommended to conduct the test once more with additional dosage form units [17, 18].

Dissolution Test 2 is specified in the USP monograph:

Phosphate buffer solution pH 7.5, 0.05 M; 900 ml. Apparatus 2: 50 rpm; use wire sinkers. Times: 1, 2, 4, 6, and 10 h. Detector: UV 276 nm. Standard solution: USP diclofenac sodium in medium.

Analysis: Pass portions of the solution under test with a suitable filter. Dilute with medium, if necessary, to a concentration similar to that of the standard solution [19]. Tolerance: as shown in **Table 1**.

Table 1. Drug Release Profile

Time (h)	Amount Dissolved
1	NMT 28%
2	20%-40%
4	35%-60%
6	50%-80%
10	NLT 65%

3. RESULTS AND DISCUSSION

The calculations had been done by taking the average absorbance of samples acquired at various time intervals and also by taking the average of the percent drug release for each sample at different time intervals. Both of these measures were taken after the samples had been obtained.

Branded 1:

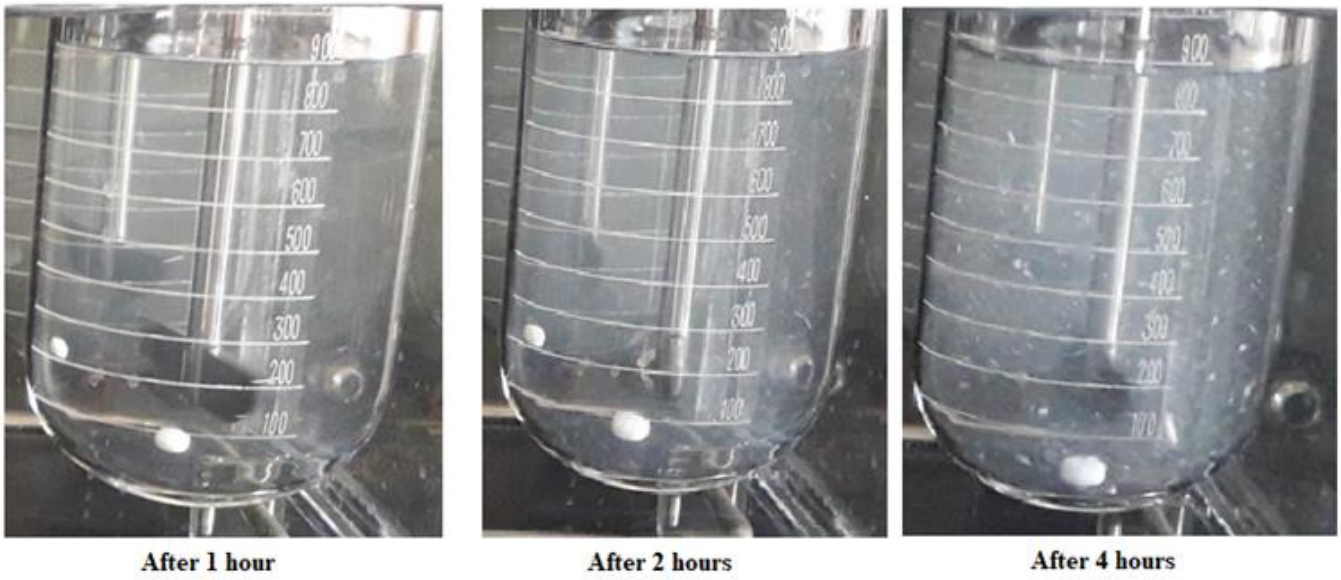


Fig 1. Visual appearance of Branded 1 at a different time interval (Branded 1)

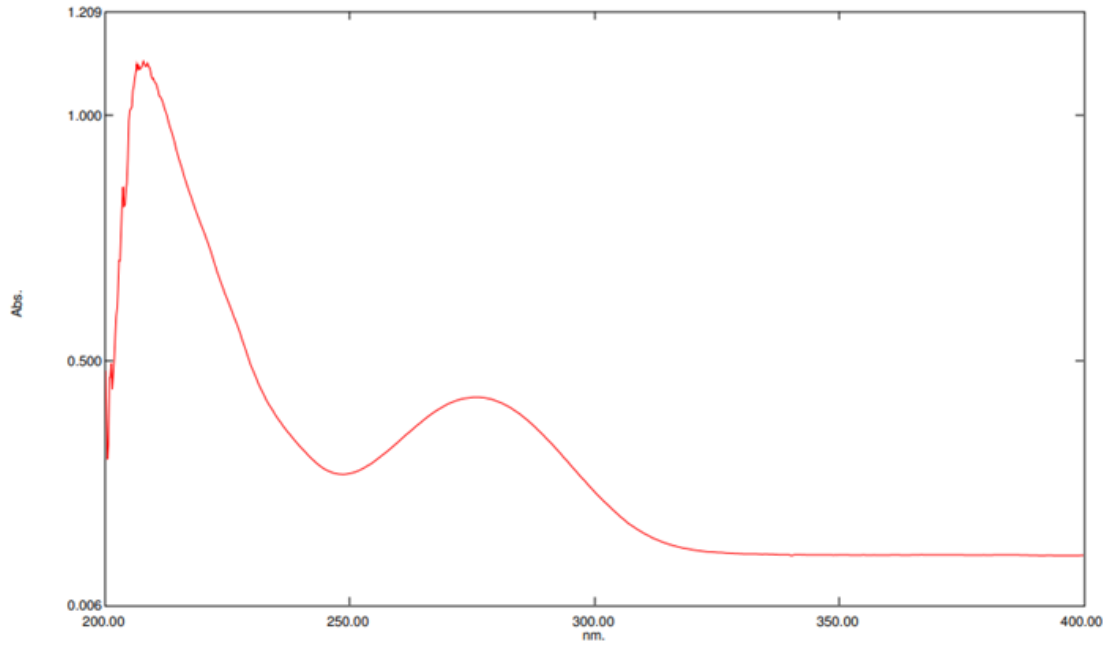


Fig 2. The UV spectrum of standard diclofenac sodium (Branded 1)

Table 2. Dissolution profile by taking average absorbance

Time Interval	Paddle 1	Paddle 2	Paddle 3	Paddle 4	Paddle 5	Paddle 6	Average absorbance	Percent Drug release
1 h	0.111	0.115	0.114	0.119	0.108	0.116	0.114	23.27%
2 h	0.145	0.160	0.162	0.167	0.161	0.159	0.159	32.50%
4 h	0.215	0.207	0.202	0.204	0.201	0.207	0.206	42.11%
6 h	0.273	0.300	0.266	0.274	0.257	0.332	0.284	57.99%
10 h	0.357	0.368	0.363	0.363	0.354	0.368	0.362	74.04%

Table 3. Dissolution profile by taking average percent drug release

Time Interval	% Drug Release						Average % Drug Release
	Vessel 1	Vessel 2	Vessel 3	Vessel 4	Vessel 5	Vessel 6	
1 h	22.69	23.51	23.30	24.32	22.08	23.71	23.27
2 h	29.65	32.72	33.13	34.15	32.92	32.51	32.51
4 h	43.98	42.35	41.33	41.74	41.12	42.35	42.15
6 h	55.86	61.39	54.44	56.08	52.59	67.94	58.05
10 h	73.08	85.33	74.31	74.31	72.47	75.33	74.14

The drug release profile was evaluated at various time intervals and found to be in compliance with the requirements outlined in the USP monograph. In a specific dissolution medium, the visual appearance of the tablet formulation can reveal the strength of the formulation for up to 4 hours.

Branded 2:

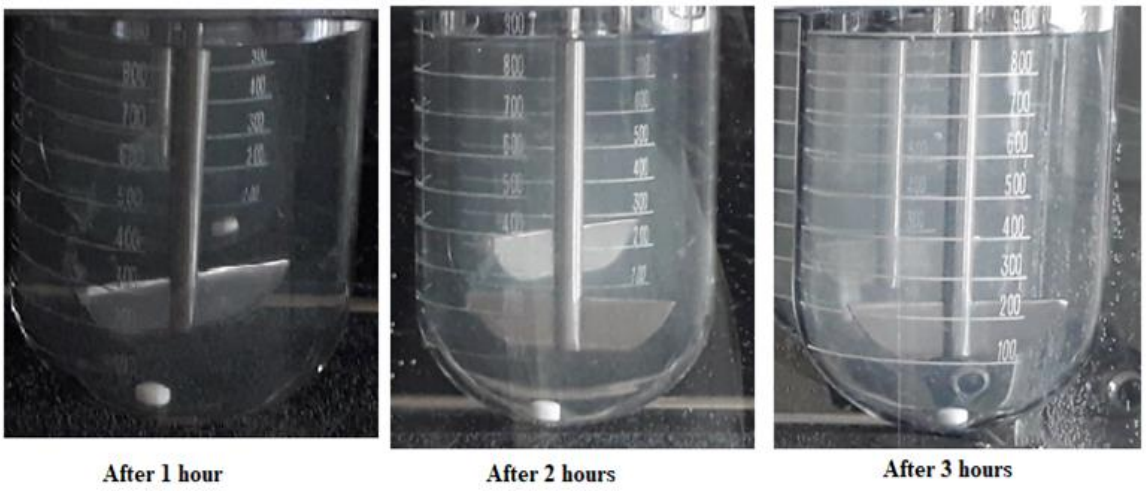


Fig 3. Visual appearance of branded 2 at different time interval (Branded 2)

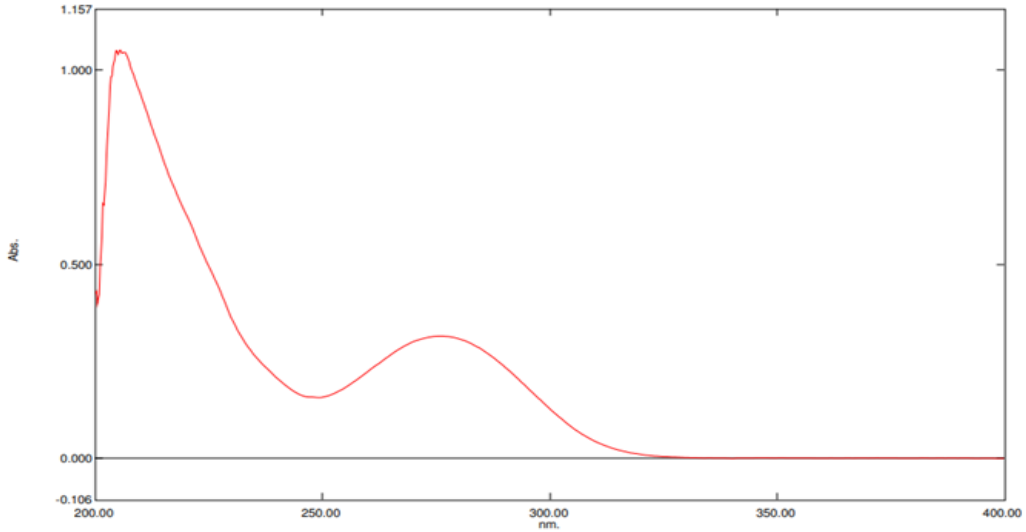


Fig 4. The UV spectrum of standard diclofenac sodium (Branded 2)

Table 4. Dissolution profile by taking average absorbance

Time Interval	Paddle 1	Paddle 2	Paddle 3	Paddle 4	Paddle 5	Paddle 6	Average Absorbance	Average % Drug release
1 h	0.059	0.069	0.068	0.081	0.070	0.066	0.069	19.70%
2 h	0.082	0.086	0.093	0.086	0.089	0.082	0.087	24.71%
4 h	0.125	0.113	0.127	0.124	0.125	0.115	0.122	34.77%
6 h	0.161	0.197	0.182	0.181	0.183	0.184	0.176	50.47%
10 h	0.237	0.224	0.245	0.242	0.236	0.241	0.238	67.97%

Table 5. Dissolution profile by taking average percent drug release

Time Interval	% Drug Release						Average % Drug Release
	Vessel 1	Vessel 2	Vessel 3	Vessel4	Vessel 5	Vessel 6	
1 h	16.89	19.75	19.46	23.18	20.04	18.89	19.70
2 h	23.48	24.62	26.63	24.63	25.77	23.48	24.77
4 h	35.80	32.37	36.37	35.51	35.80	35.95	34.80
6 h	46.13	47.86	52.15	51.86	52.44	52.73	50.52
10 h	67.91	67.05	70.20	69.38	67.62	69.05	68.54

The drug release profile was evaluated at various time intervals and found to be in compliance with the requirements outlined in the USP monograph. In a specific dissolution medium, the visual appearance of the tablet formulation can reveal the strength of the formulation for up to 4 hours.

Generic 1:

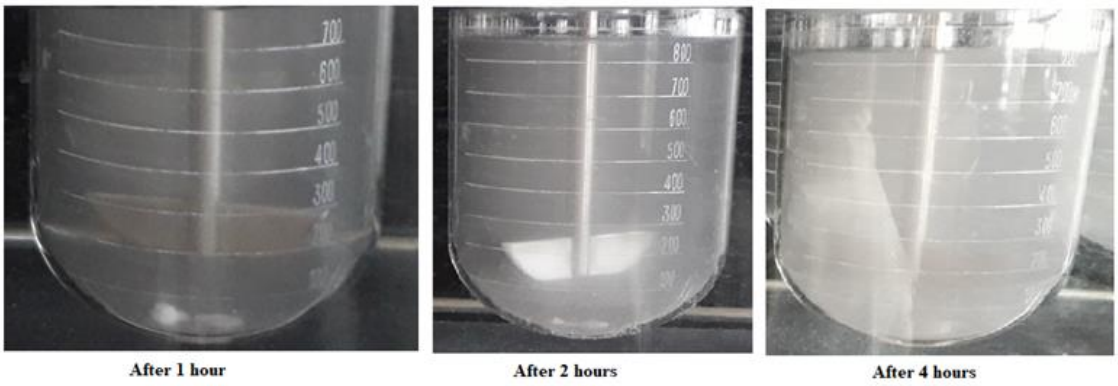


Fig 5. Visual appearance of Generic 1 at different time interval (Generic 1)

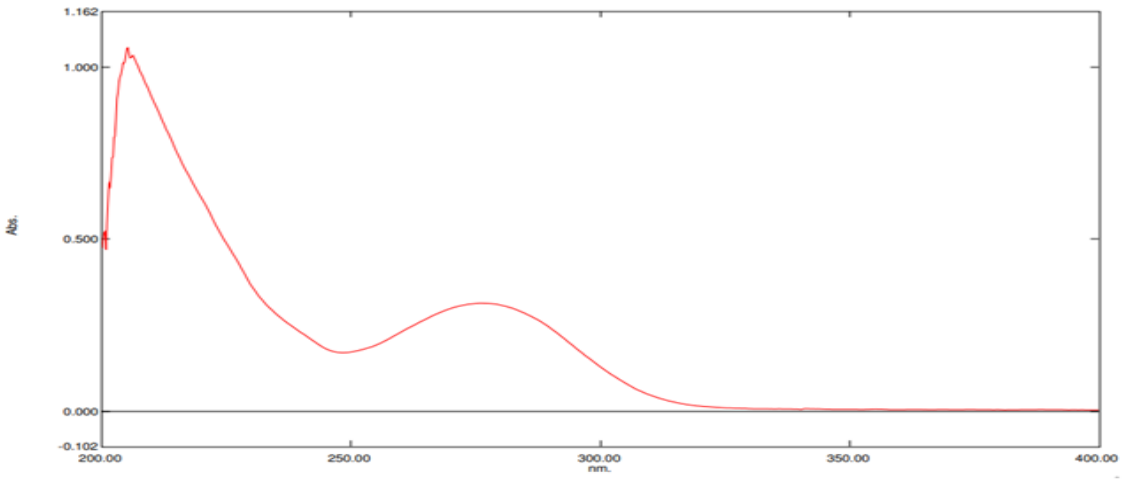


Fig 6. The UV spectrum of standard diclofenac sodium (Generic 1)

Table 6. Dissolution profile by taking average absorbance

Time Interval	Paddle1	Paddle2	Paddle3	Paddle4	Paddle5	Paddle6	Average Absorbance	Percent Drug Release
1 h	0.138	0.122	0.210	0.139	0.182	0.157	0.158	43.92%
2 h	0.233	0.252	0.277	0.230	0.295	0.289	0.263	73.02%
4 h	0.364	0.354	0.334	0.345	0.372	0.364	0.356	98.83%
6 h	0.346	0.377	0.342	0.331	0.356	0.344	0.352	97.95%
10 h	0.388	0.357	0.353	0.343	0.370	0.365	0.363	100.83%

Table 7. Dissolution profile by taking average percent drug release

Time Interval	% Drug Release						Average % Drug Release
	Vessel 1	Vessel 2	Vessel 3	Vessel 4	Vessel 5	Vessel 6	
1 h	38.37	34.47	58.38	38.64	50.60	43.65	44.02
2 h	64.80	70.08	77.03	63.96	82.04	80.37	73.05
4 h	101.27	98.49	92.93	95.99	103.49	101.27	98.91
6 h	101.32	91.03	95.21	92.15	99.10	95.76	95.76
10 h	108.05	99.43	98.32	95.54	103.05	101.66	101.01

The drug release profile at different time intervals does not comply with the specifications specified in the USP Monograph. In addition, the visual appearance did not show the strength of the tablet formulation in the given dissolution medium for up to 4 hours.

Generic 2:

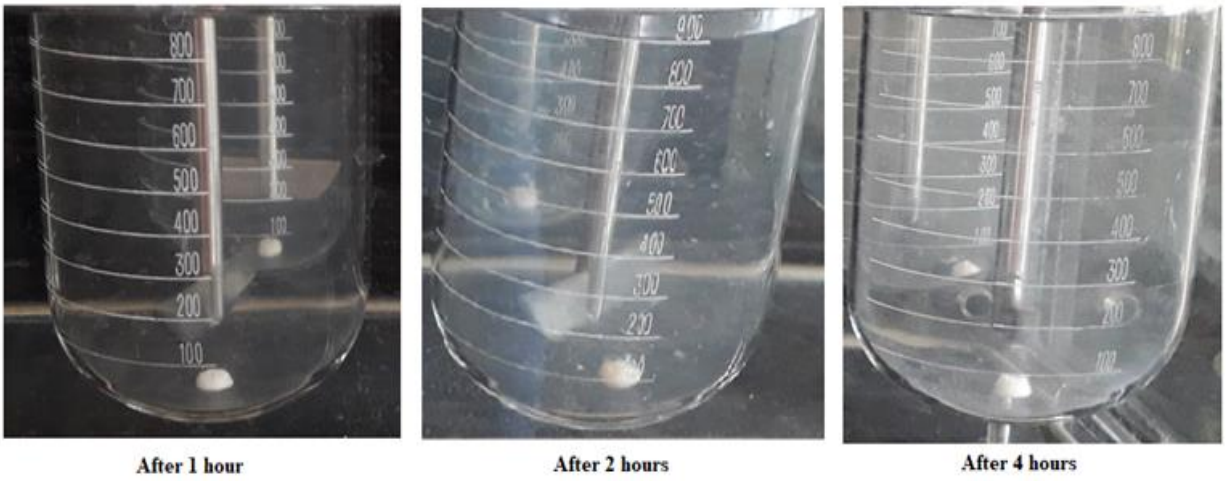


Fig 7. Visual appearance of Generic 2 at different time interval (Generic 2)

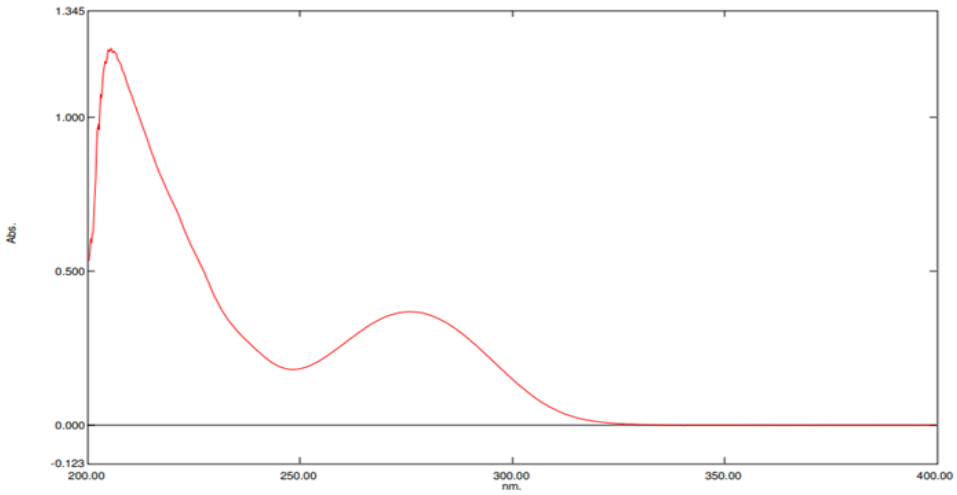


Fig 8. The UV spectrum of standard diclofenac sodium (Generic 2)

Table 8. Dissolution profile by taking average absorbance

Time Interval	Paddle1	Paddle2	Paddle3	Paddle4	Paddle5	Paddle6	Average Absorbance	Percent Drug Release
1 h	0.058	0.056	0.067	0.054	0.045	0.049	0.054	13.00%
2 h	0.083	0.087	0.083	0.082	0.081	0.076	0.082	19.45%
4 h	0.163	0.145	0.156	0.144	0.146	0.137	0.148	35.22%
6 h	0.213	0.211	0.219	0.207	0.209	0.207	0.211	50.05%
10 h	0.313	0.297	0.340	0.304	0.350	0.302	0.317	75.35%

Table 9. Dissolution profile by taking average percent drug release

Time Interval	% Drug Release						Average % Drug Release
	Vessel 1	Vessel 2	Vessel 3	Vessel 4	Vessel 5	Vessel 6	
1 h	13.76	13.28	15.89	12.89	10.67	10.20	12.76
2 h	19.70	20.65	19.70	19.46	19.22	18.03	19.46
4 h	38.69	34.41	37.02	34.18	34.66	87.79	44.46
6 h	50.56	50.09	51.98	49.15	49.62	49.15	50.09
10 h	44.32	70.53	80.73	72.19	85.47	71.71	75.83

The drug release profile at various time intervals is in compliance with the parameters provided in the USP Monograph, with the exception of the 2-hour time period. In a specific dissolution medium, the visual appearance of the tablet formulation can reveal the strength of the formulation for up to 4 hours.

Generic 3:

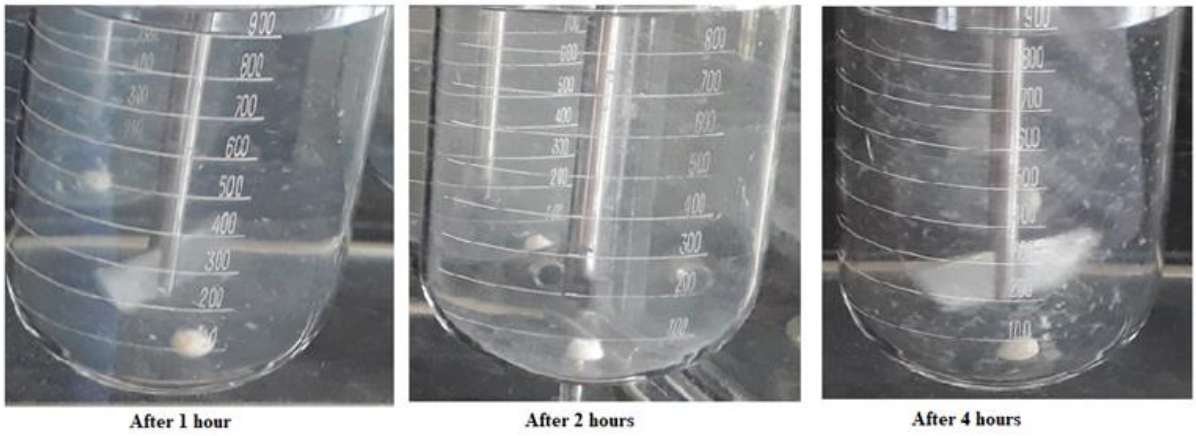


Fig 9. Visual appearance of Generic 3 at different time interval (Generic 3)

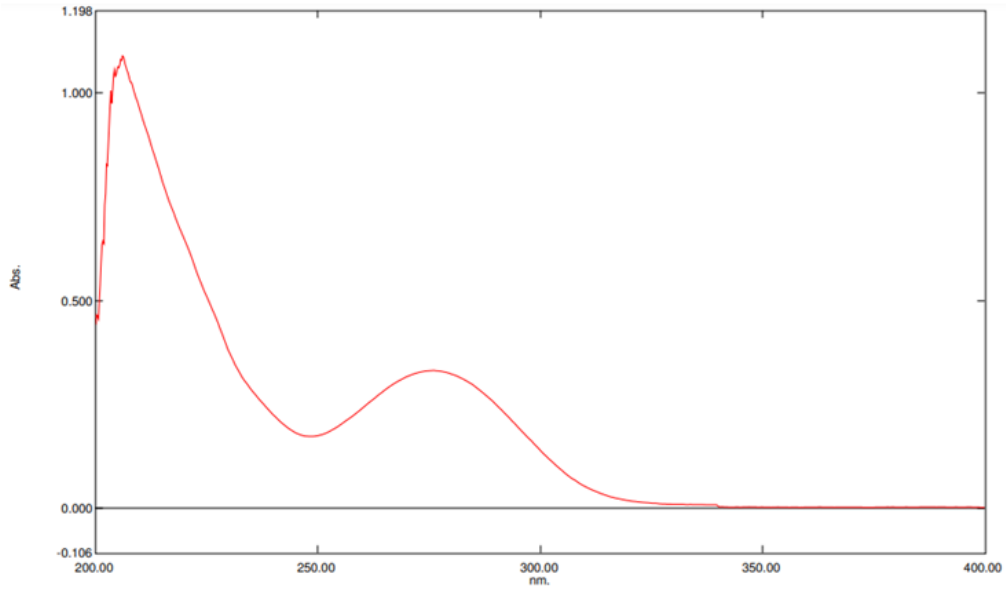


Fig 10. The UV spectrum of standard diclofenac sodium (Generic 3)

Table 10. Dissolution profile by taking average absorbance

Time Interval	Paddle 1	Paddle 2	Paddle 3	Paddle 4	Paddle 5	Paddle 6	Average Absorbance	Percent Drug Release
1 h	0.036	0.020	0.015	0.020	0.016	0.021	0.021	5.59%
2 h	0.131	0.135	0.132	0.158	0.135	0.155	0.141	36.96%
4 h	0.257	0.258	0.252	0.238	0.236	0.239	0.247	64.69%
6 h	0.340	0.322	0.316	0.322	0.312	0.364	0.329	86.40%
10 h	0.372	0.388	0.372	0.393	0.369	0.359	0.376	98.60%

Table 11.Dissolution profile by taking average percent drug release

Time Interval	% Drug Release						Average % Drug Release
	Vessel 1	Vessel 2	Vessel 3	Vessel 4	Vessel 5	Vessel 6	
1 h	9.44	5.24	3.93	5.24	4.19	5.05	5.52
2 h	34.34	35.39	35.13	41.68	35.39	40.63	37.09
4 h	67.39	67.66	66.08	62.41	61.89	62.68	64.69
6 h	89.18	84.46	82.88	84.46	81.83	95.47	86.38
10 h	97.57	101.77	97.57	103.08	96.79	94.17	98.49

Except for at 4 and 6 hours, the drug release profile at various time intervals corresponds with the parameters provided in the USP monograph. In a specific dissolution medium, the visual appearance of the tablet formulation can reveal the strength of the formulation for up to 4 hours.

Comparative drug release profile by average absorbance

Table 12. Comparative drug release profile by average absorbance

Sr. No.	Time Interval	Release Profile					Acceptance criteria
		Branded 1	Branded 2	Generic 1	Generic 2	Generic 3	
1.	1 h	23.27%	19.70%	43.92%	13.00%	5.59%	NMT 28%
2.	2 h	32.51%	24.72%	73.04%	19.46%	36.96%	20%-40%
3.	4 h	42.14%	35.16%	98.90%	35.24%	64.69%	35%-60%
4.	6 h	58.04%	50.52%	97.96%	50.08%	86.40%	50%-80%
5.	10 h	74.04%	68.07%	101.07%	75.45%	98.60%	NLT 65%

Table 13. Comparative drug release profile by average percent drug release

Sr. No.	Time Interval	Average % Release Profile					Acceptance criteria
		Branded 1	Branded 2	Generic 1	Generic 2	Generic 3	
1.	1 h	23.27	19.70	44.02	12.76	5.52	NMT 28%
2.	2 h	32.51	24.77	73.05	19.46	37.09	20%-40%
3.	4 h	42.15	34.80	98.91	44.46	64.69	35%-60%
4.	6 h	58.05	50.52	95.76	50.09	86.38	50%-80%
5.	10 h	74.14	68.54	101.01	75.83	98.49	NLT 65%

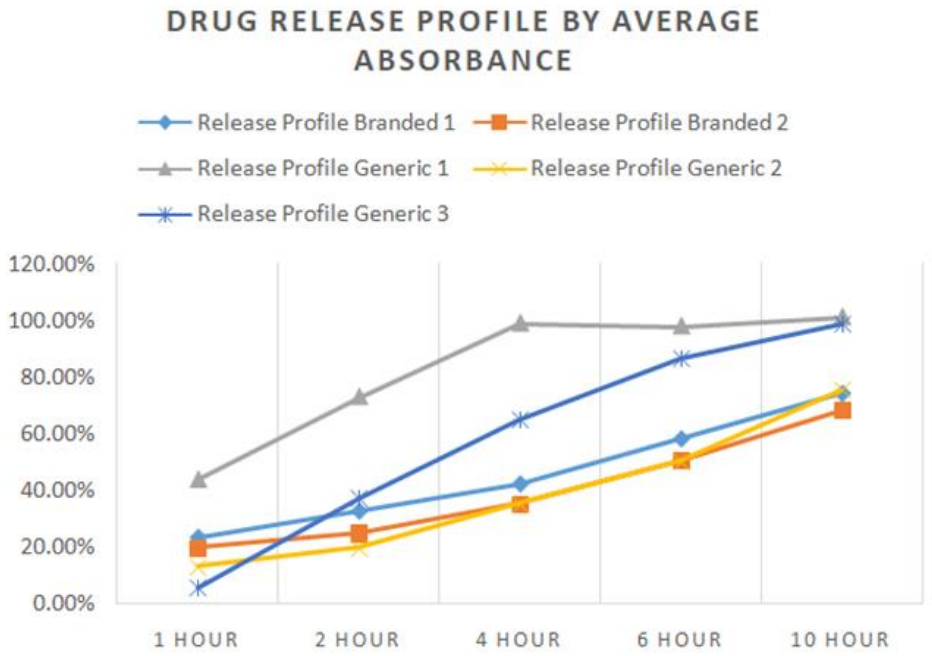


Fig 11. Graphical representation of drug release profile by average absorbance

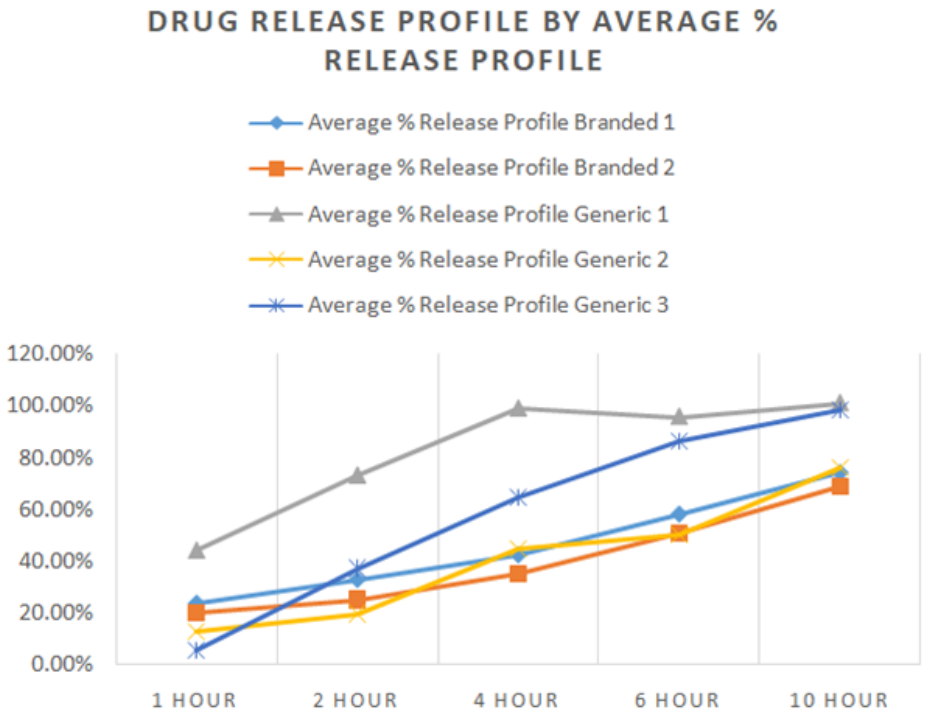


Fig 12. Graphical representation of drug release profile by average percent release

The dissolution qualities of tablets were evaluated, and the results showed that both Brand 1 and Brand 2 met the USP requirements. However, the dissolution profiles of each brand showed a substantial difference, which related to a different method of tablet processing. Both

Branded 1 and Branded 2 demonstrate a release that is consistent with the stated criteria and preserves its qualities, which indicate that the formulation for prolonged release is done correctly. Generic 1 only displays excess release within one hour, does not show release according to the specifications, and may suggest that the delayed release formulation is faulty. Both Generic 2 and Generic 3 demonstrate consistent release that builds up cumulatively over time; however, neither formulation satisfies the requirements of the USP criteria. Figure 11 depicts a graphic representation of the drug release profile using the average absorbance of different formulation samples. A graphic illustration of the medication release profile by average percent release is shown in Figure 12.

CONCLUSION

The results of the study demonstrate that branded formulations sold by branded pharmaceutical companies exhibit release that is consistent with USP criteria. However, formulations produced by local brands do not meet the standards requirements. In addition, unlike local products, the visual appearance of branded formulations suggests that the tablet will remain intact in the recommended dissolution medium for upto 4 hours.

Throughout the duration of the study, we observed that the Indian pharmacopoeia does not specify acceptance criteria in the monograph of diclofenac sodium extended release tablet for the dissolution test, only a general statement. The United States Pharmacopoeia (USP) is well-known for its stringent requirements, despite the fact that it specifies a variety of dissolve processes and acceptability criteria for each.

According to the findings of the study, there may be room for improvement in the current constraints governing the product approval procedure. It is also recommended that enterprises adhere to the rules governing the quality of medicines.

Consent for publication

All the authors approved the manuscript for publication.

Availability of data and material

All required data is available.

Conflict of interest

The authors declare that they have no conflict of interest.

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Both authors have equal contributions.

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