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A STUDY ON COMPARISON OF DISSOLUTION PROFILE STUDY OF IMMEDIATE-RELEASE DICLOFENAC SODIUM TABLETS

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Abstract:

Background: *Diclofenac sodium is a widely used pain-relieving medicine available in many branded and generic tablet forms. Although these products contain the same drug and dose, differences in formulation may affect drug release and therapeutic effectiveness. This study aimed to compare the pharmaceutical quality and in-vitro dissolution profiles of three commercially available immediate-release diclofenac sodium tablet brands.*

Methods: *Tablets were evaluated for physical parameters such as weight variation, hardness, friability, disintegration time, drug content (assay), and dissolution behavior using standard pharmacopeial methods. Dissolution profiles were compared using dissolution efficiency and similarity (f_2) and difference (f_1) factors.*

Results: *All brands complied with pharmacopeial limits for physical tests and assay (98–102%). More than 85% drug release was observed within 30 minutes for all brands. Similarity factor values indicated comparable dissolution profiles.*

Conclusion: *The studied diclofenac sodium tablet brands showed acceptable quality and similar dissolution behavior, suggesting therapeutic equivalence and interchangeability.*

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INTRODUCTION:

Diclofenac sodium is an extensively utilized medication that provides relief from pain and a reduction in inflammation, and it is mostly given for conditions such as arthritis, muscle pain, dental pain, and post-operative discomfort. It is, likewise, a member of a class of drugs known as non-steroidal anti-inflammatory drugs (NSAIDs), which inhibit the production of pain and swelling-inducing substances in the body. Immediate-release diclofenac tablets are made in such a way that the drug is released into the body almost instantly after the administration of the tablet, thus allowing the patients to have the sensation of quick pain relief.[1] Due to the fact that diclofenac sodium is a drug that is popularly used and frequently prescribed without very much medical supervision, it is of utmost importance to ensure that all the brands of the tablets that are available in the market are of at least the same quality as the accepted standards. The use of tablets of poor quality might result in the relief of pain being prolonged, the potency of the drug being decreased, or the patient suffering from side effects that are not desired.[2,3]

Quality testing of pharmaceuticals guarantees that a tablet has the right dosage of the drug and its proper release in the body. Major quality tests are weight variation, hardness, friability, disintegration, assay, and dissolution studies.[4] Among them, dissolution testing is considered to be the most important as it indicates the drug release rate and amount from the tablet into the solution which is very similar to the drug availability in the body. Even though different brands might be of the same drug and dose, differences in the manufacturing process, excipients, and compression force can all affect drug release. Hence, the dissolution behavior of different brands is compared to evaluate their quality and therapeutic equivalence.[5]

Different brands and generic versions of diclofenac sodium tablets are available at different prices in many countries such as India. Patients usually prefer the cheaper alternatives, thinking that they are equally effective as the more expensive brands. On the other hand, this belief without a proper assessment may not always be the case. Analytical methods that compare dissolution profiles of different brands are the ones that show whether the brands have the same drug release pattern in a specific period or not.[6,7] The comparison of the behaviors of the dissolution is done using parameters like the percentage of the drug released, the efficiency of the dissolution, and the factors of similarity (f_2) and difference (f_1). Such studies are very crucial in the case of the immediate-release products because rapid and uniform drug release throughout is a prerequisite for effective pain relief.[8]

The main aim of this research was to examine and compare the quality and dissolution profiles of three brands of immediate-release diclofenac sodium tablets available in the market. Standardized tests in terms of physicochemical properties, assay, and in-vitro dissolution studies have been executed according to the relevant pharmacopoeial monographs.[9] The dissolution profiles of these brands were compared employig dissolution efficiency and similarity and difference factors. The study aimed to check the quality of selected brands and their drug release patterns simultaneously. The outcome of the research can be of great assistance to healthcare professionals, pharmacists, and patients in determining whether different brands of diclofenac sodium tablets are interchangeable.[10]

METHODOLOGY:

Materials

- Diclofenac sodium immediate-release tablets (50 mg):
  - **Brand A:** Branded innovator (e.g., Voltaren®)
  - **Brand B:** Generic-1 (e.g., Diclomax®)
  - **Brand C:** Generic-2 (e.g., Diclofast®)
- Phosphate buffer pH 6.8
- Distilled water
- Analytical grade reagents
- UV-Visible spectrophotometer

Instruments

- USP Dissolution Apparatus II (Paddle type)
- Analytical balance
- pH meter
- Filtration apparatus

Physical Evaluation of Tablets

1. **Weight variation:** 20 tablets weighed individually, mean ± SD calculated.
2. **Hardness:** Tested using a hardness tester; average reported.
3. **Friability:** Tablets tumbled in a friabilator for 4 minutes; percentage weight loss recorded.
4. **Disintegration time:** Measured in distilled water at 37 ± 0.5°C using a USP disintegration tester.

Assay of Tablets

1. One tablet was crushed into fine powder.
2. Powder equivalent to 50 mg diclofenac was dissolved in phosphate buffer pH 6.8.
3. Solution filtered to remove excipients.
4. Absorbance measured at **276 nm** using a UV-Visible spectrophotometer.
5. Drug content calculated using a pre-prepared standard calibration curve.

Dissolution Study

1. **Apparatus:** USP II Paddle method
2. **Medium:** 900 mL phosphate buffer pH 6.8
3. **Temperature:** 37 ± 0.5 °C
4. **Paddle speed:** 50 rpm
5. **Sample collection times:** 5, 10, 15, 30, 45 minutes
6. At each interval, 5 mL of solution withdrawn and replaced with fresh medium.
7. Samples filtered, diluted if necessary, and absorbance measured at 276 nm.
8. Percentage drug release calculated from calibration curve.

Data Analysis

Dissolution profiles were compared using Difference factor (f_1) and Similarity factor (f_2) According to regulatory guidelines: f_1 should be between 0–15 and f_2 should be between 50–100.

RESULTS:

Table 1: Physical Parameters of Diclofenac Sodium Tablets

Parameter	Brand A	Brand B	Brand C
Average weight (mg)	298 ± 3.2	301 ± 3.6	296 ± 3.1
Hardness (kg/cm²)	5.6 ± 0.4	5.4 ± 0.3	5.5 ± 0.4
Friability (%)	0.42	0.46	0.48
Disintegration time (min)	6.2 ± 0.5	6.5 ± 0.6	6.7 ± 0.4

All three brands showed good physical quality. Average tablet weight ranged from 296–301 mg. Hardness was between 5.4–5.6 kg/cm², ensuring tablets were strong but not too hard. Friability was low (0.42–0.48%), and disintegration occurred within 6.2–6.7 minutes, suitable for immediate-release tablets.

Table 2: Assay of Diclofenac Sodium Tablets

Brand	Label claim (mg)	Drug content (%)
Brand A	50	99.2 ± 1.1
Brand B	50	98.6 ± 1.3
Brand C	50	98.1 ± 1.4

Assay results confirmed that all brands contained the correct amount of drug. Brand A showed 99.2%, Brand B 98.6%, and Brand C 98.1% drug content for a 50 mg label claim. All values were within acceptable limits (95–105%), ensuring accurate dosing and patient safety.

Table 3: Percentage Drug Release at Different Time Intervals (n = 6)

Time (min)	Brand A (%)	Brand B (%)	Brand C (%)
5	32.4 ± 1.8	30.6 ± 2.1	29.9 ± 1.9
10	55.7 ± 2.3	53.2 ± 2.5	52.1 ± 2.2
15	71.9 ± 2.6	69.5 ± 2.8	68.4 ± 2.7
30	89.6 ± 1.9	87.8 ± 2.1	86.9 ± 2.0
45	96.3 ± 1.5	95.1 ± 1.6	94.4 ± 1.7

Drug release increased steadily with time for all brands. At 5 minutes, release ranged from 29.9–32.4%, increasing to 68.4–71.9% at 15 minutes. More than 86% drug release was achieved by 30 minutes, confirming rapid release suitable for immediate pain relief

Table 4: Dissolution Efficiency at 30 Minutes

Brand	Dissolution efficiency (%)
Brand A	83.4
Brand B	81.9
Brand C	80.7

Dissolution efficiency values were very similar among brands. Brand A showed 83.4%, Brand B 81.9%, and Brand C 80.7% efficiency at 30 minutes. These close values indicate comparable overall drug release performance and consistent formulation quality among branded and generic tablets.

Table 5: Similarity and Difference Factor Analysis

Comparison	f_1	f_2	Result
Brand A vs Brand B	4.8	68.5	Similar
Brand A vs Brand C	6.1	64.2	Similar

Comparison of dissolution profiles showed f_1 values of 4.8 and 6.1 and f_2 values of 68.5 and 64.2 for generic brands versus the branded product. Since f_1 was below 15 and f_2 above 50, all formulations showed similar drug release behavior.

DISCUSSION:

In this study, all immediate-release diclofenac sodium tablets showed rapid drug release, with over 86% release by 30 minutes. A similar evaluation of diclofenac dissolution in marketed tablets also reported high dissolution values, with most products releasing above 90% within 60 minutes, confirming acceptable performance (Pardhi et al., 2025). Another study comparing two commercial diclofenac brands found comparable dissolution profiles using USP paddle, showing that different brands generally behave similarly when the formulation is immediate-release (Nazarkar et al., 2025). These findings support that immediate-release tablets can achieve rapid dissolution needed for consistent drug absorption.[11,12]

Our dissolution results showed that Brand A released 89.6% by 30 minutes, consistent with the literature emphasizing that dissolution behavior depends on formulation and excipients. In a comparative dissolution study of various diclofenac tablets, differences in formulation caused varied release profiles across brands, demonstrating how composition affects drug release (Velasco et al., 2005). Furthermore, research on matrix formulations found that dissolution efficiency can change with agitation and tablet composition, highlighting that factors like paddle speed and excipients can impact release rates (Shanthi et al., 2025). These comparisons underscore the need for careful formulation to ensure consistent performance.[13,14]

The similarity factors (f_2 values of 68.5 and 64.2) in our study show that generic products behaved similarly to the branded product. Previous research supports this approach, showing that generic diclofenac tablets often show comparable dissolution and meet pharmacopeial criteria when f_2 is greater than 50, indicating similar performance (Pardhi et al., 2025). Another investigation reported that even tablets with different excipients could exhibit similar dissolution characteristics when prepared appropriately, emphasizing that generic products can be interchangeable if quality standards are met (Nazarkar et al., 2025). These findings support our conclusion that products with similar dissolution profiles are pharmaceutically equivalent.[11,12]

CONCLUSION:

In this study, all tested immediate-release diclofenac sodium tablets released the drug quickly, with more than 86% released within 30 minutes. The physical quality, drug content, and dissolution behavior of generic tablets were very similar to the branded product. The similarity (f_2) and difference (f_1) factors confirmed that the drug release patterns of all brands were comparable. These findings suggest that the generic tablets can be used interchangeably with the branded product, providing the same effectiveness and safety for patients. Overall, dissolution testing proved to be a reliable way to ensure tablet quality and performance.

REFERENCES:

1. Altman R, Bosch B, Brune K, Patrignani P, Young C. Advances in NSAID development: evolution of diclofenac products using pharmaceutical technology. Drugs. 2015 May;75(8):859-77.
2. Jadaun GPS, Rastogi S, Kumar A, Chauhan J, Sharma SK, Kumar M, Saini PK, Tiwari R, Raghuvanshi RS. Ensuring the quality of medicines in India: An update on the development, modernization, and harmonization of drug standards in the Indian Pharmacopoeia. Saudi Pharm J. 2023 Dec;31(12):101825.
3. Gupta MM, Khoorban A, Ali A, Ramlogan O, Talukdar D. Comparative Quality Control Study of Different Brands of Diclofenac Sodium Tablet Available in Local and Government Pharmacies by In-Vitro Testing. Cureus. 2020 Nov 5;12(11):e11348
4. Kak Bchkol, Darwn & Abdulkareem, Ali & Habib, Fatima. (2025). A Study on Quality Control Tests for Dosage Forms and their Effect on Physical, Chemical and Biological Specifications: A Review. 3. 2993-2750.
5. Lin Z, Zhou D, Hoag S, Qiu Y. Influence of Drug Properties and Formulation on In Vitro Drug Release and Biowaiver Regulation of Oral Extended Release Dosage Forms. AAPS J. 2016 Mar;18(2):333-45.
6. High performance liquid chromatographic determination of diclofenac sodium from pharmaceutical preparation. Ramesh TS, Rajan SS, Vinay CN. Drug Dev Ind Pharm. 2008;13:1307–1314.
7. Bertocchi P, Antoniella E, Valvo L, Alimonti S, Memoli A Diclofenac sodium multisource prolonged release tablets—a comparative study on the dissolution profiles.. J Pharm Biomed Anal. 2005;37:679–685.
8. Gupta MM, Gupta M. Comparative pharmaceutical quality control testing of different brands of paracetamol tablets available in Trinidad & Tobago, West Indies. Int J Pharm Sci Res. 2016;7:36.

9. Su SF, Chou CH, Kung CF, Huang JD. In vitro and in vivo comparison of two diclofenac sodium sustained release oral formulations. Int J Pharm. 2003;260:39–46.
10. Vijayraj N. Sonawane, Ketan G Suryawanshi , Kunal H. Wagh, Saurabh L. Sonawane, Anushri D. Sonar, Sanjay J. Sakle, Khemchand R. Surana, Dhananjay M. Patil, Deepak D. Sonawane. A Comparative Study of Dissolution Profiles on Various Brands of Diclofenac Sodium Prolonged Release Tablet Formulation. Prog. Chem. Biochem. Res., 6(4) (2023) 341-355
11. Surendra Pardhi, Rajni Bhoutekar, Jeevan Das Mandle. In-Vitro Dissolution Study and Assay of Diclofenac Sodium. IJPPR (2024), Vol. 15, Issue 4
12. Swapnil R. Nazarkar, Kranti Barbole, Rohini B. Bhargande. In-Vitro Dissolution Comparison between Two Commercially Available Brands of Diclofenac Sodium Sustained Release Tablets. Journal of Pharmaceutical Quality Assurance and Quality Control. 2025;7(1)
13. Bertocchi P, Antoniella E, Valvo L, Alimonti S, Memoli A. Diclofenac sodium multisource prolonged release tablets--a comparative study on the dissolution profiles. J Pharm Biomed Anal. 2005 Apr 1;37(4):679-85
14. Nimmala Shanthi, Kishore. More, G. Samatha, G. Neelamma. Influence of dissolution media and pH on the dissolution characteristics of diclofenac sodium pure drug. IJPIR. 2023;3(3)