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Original Research Article

A comparative study of the *in vitro* dissolution rate and Acid-Neutralizing capacity of Aceproxyvon with other marketed drugs

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ABSTRACT

Background: Quality is one of the most important issues in the pharmaceutical industry. Drugs must be marketed as safe and therapeutically effective formulations whose performance is consistent and foreseeable. *In vitro* evaluation verifies and ensures their quality, bioavailability, and optimum therapeutic activity. Aceclofenac and Paracetamol (acetaminophen) are commonly used for the relief of headaches and pain. The combination of these two drugs is available in different brands in the Indian market. The main objective of the present study was to conduct a comparative *in vitro* dissolution release test and acid neutralizing capacity test (ANC) of Test products versus Reference products.

Methods: Brands that are similar in both composition and concentration were used in the study to compare the in vitro dissolution profile and ANC in different pH buffer solutions. Three marketed brands of Aceclofenac 100 mg and Paracetamol 325 mg, i.e., Aceproxyvon (test product Brand A), Brand B, and Brand C (Reference products), were used in the study. Brand D being an antacid was used as a reference product to compare the acid-neutralizing capacity of the drugs.

Results: The dissolution rates of paracetamol were similar across all formulations at various pH mediums. Aceclofenac showed a higher dissolution rate in Brand A as compared to Brand B and C at pH 4.5, while the dissolution rates of aceclofenac were comparable in all formulations using pH 6.8 and pH 7.5 phosphate media. The ANC of Brand A was found to be higher (7.42 mEq/g) compared to Brand B (6.74 mEq/g) and Brand C (7.18 mEq/g).

Conclusion: Brand A showed faster dissolution and higher acid neutralizing capacity as compared to reference products. This enhancement in dissolution rate may further result in a rapid onset of action and better therapeutic efficacy.

1. Introduction

Paracetamol and Aceclofenac are the most commonly used drugs for pain and inflammation across the world.[1,2] Aceclofenac (2-[(2, 6-dichlorophenyl)amine] phenyl acetoxy acetic acid) is a non-steroidal anti-inflammatory drug (NSAID) of the phenylacetic acid group that possesses remarkable anti-inflammatory, analgesic, and antipyretic properties. It is commonly used to treat rheumatoid arthritis, osteoarthritis, and ankylosing spondylitis pain and inflammation.[3,4] Aceclofenac shows a comparatively higher anti-inflammatory action than conventional NSAIDs.[5] Paracetamol is also known as Acetaminophen N-(4-hydroxyphenyl) acetamide.[6] It is a widely used over-the-counter analgesic and antipyretic indicated for temporary relief of pain and discomfort associated with headaches,

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osteoarthritis, arthritis, muscle aches, etc.[7] Both of the drugs work by inhibiting the production of prostaglandin by selectively inhibiting cyclooxygenases i.e., COX-1 and COX-2, which eventually reduces pain, swelling, and inflammation. Paracetamol is usually combined with Aceclofenac for better patient acceptance, greater potency, fewer side effects, and rapid relief.[2]

Aceclofenac shows prolonged analgesic effect than that of Paracetamol. The addition of Paracetamol to NSAIDS will increase its effects and decrease dose-dependent side effects. A combination of Aceclofenac (with its peripheral effect) and Paracetamol (with its central effect) will give better analgesic efficacy than individual drugs.[2] Aceproxyvon is a combination of Paracetamol 325 mg and Aceclofenac 100 mg. Drug quality is one of the most important factors in ensuring that drugs are safe and therapeutically active.[8]

The neutralizing and buffering capability of each antacid determines its efficacy. ANC, stated in milliequivalents (mEq), is the amount of acid that can be neutralized using one standard dose of an antacid. The most effective antacids should have a high ANC that can be estimated by back titration which is a static test used for comparison of the level of neutralization achieved by a range of antacids through in vitro experiments.[9]

NSAIDs and analgesics are some of the most commonly used medicines. NSAIDs acts by inhibiting COX-2 to provide therapeutic anti-inflammatory and analgesic effects. Drugs that inhibit the COX-1 isoform have toxicity for the gastric and renal. COX-2 inhibition may possibly play a function in mucosal damage. Every NSAID has some level of gastrointestinal toxicity.[10] ANC plays a crucial role in alleviating acid-related side effects by providing a buffering effect in the stomach.[11] Hence, ANC is important for analgesic drugs.

A drug dissolution test is a qualitative and quantitative tool, which is one of the in vitro tests that helps to determine the quality of oral pharmaceutical solid dosage forms such as tablets and capsules. This test gives some important information about the biological availability of a drug and also the batch-to-batch consistency of products.[7] The main purpose of a solid dosage form is to make a drug available to the human body at a certain rate and in a defined amount through the gastrointestinal tract (GIT) so that the drug can produce pharmacological effects. However, studies on the bioavailability of drugs in a given dosage form revealed that, in many situations, solid dosage forms did not give the same therapeutic effects. This is mostly caused by the drug's insufficient dissolution and subsequent absorption from the GIT. Consequently, a crucial test of product quality is the dissolution analysis of pharmaceutical solid dosage forms. The dissolution characteristic of a drug in its dosage form depends on many factors, including its formulation and manufacturing process.[12]

Despite the fact that there are many marketed products with the same active ingredients and additives as the study product, the production method may vary. This study deals with the comparison of the in vitro dissolution rate and acid-neutralizing capacity of Aceproxyvon and marketed formulations.

2. Materials and Methods

The study methodology includes acid-neutralizing capacity and in vitro dissolution release rate procedures.

2.1. Test and reference products

2.1.1. Test

Brand A- Aceproxyvon Tablets, (Paracetamol 325 mg and Aceclofenac 100 mg) (Dr. Reddy's Laboratories) with the Reference: Brand B- HIFENAC P tablets; Paracetamol 325mg and Aceclofenac 100mg of Intas Pharmaceuticals Limited; Brand C- ZERODOL P tablets; Paracetamol 325mg and Aceclofenac 100mg of IPCA Laboratories Limited; and Brand D- GELUSIL tablets of Pfizer.

2.2. Acid neutralizing capacity study

Reagents: Sodium Hydroxide (NaOH) pellets, AR grade, Hydrochloric Acid (HCl), High-performance liquid chromatography (HPLC) grade; and Water, Milli-Q.

Equipment: Magnetic stirrer, Calibrated pH meter, motor & pestle and burette.

Preparation of 0.5 N NaOH Solution: Add 300 mL of water to a 500 mL volumetric flask, add about 10 g of NaOH pellets, sonicate to dissolve, makeup to the mark with Milli Q water, and mix.

Preparation of 1.0 N HCl Solution: Add 300 mL of water to a 500 mL volumetric flask, add about 42.5 mL of concentrated HCl, sonicate to dissolve, makeup to the mark with Milli Q water, and mix.

2.2.1. Test procedure for Non-chewable tablets

Weigh not less than 20 tablets. Grind the tablets to a fine powder and transfer it into a 250 mL beaker. Add 70 mL of water and stir it for 1 minute. Pipette out 30 mL of 1.0 N HCl volumetric solution into the test preparation (250 mL beaker) while continuing to stir the magnetic stirrer. Stir for 15 minutes accurately after the addition of the acid and begin titration immediately. In a period not to exceed 5 minutes, titrate the excess HCl with a 0.5 N NaOH volumetric solution to attain a stable (for 10 to 15 seconds) pH 3.5.

2.2.2. Test procedure for chewable tablets

Transfer 1 tablet to a 250 mL beaker. Add 50 mL of water and stir it for 1 minute. Pipette 30 mL of 1.0 N HCl volumetric solution into the test preparation (250 mL

beaker) while continuing to stir the magnetic stirrer. Stir for 15 minutes, accurately after the addition of the acid and begin titration immediately. In a period not to exceed 5 minutes, titrate the excess HCl with a 0.5 N NaOH volumetric solution to attain a stable (for 10 to 15 seconds) pH 3.5.

The Total mEq of acid consumed was calculated by using the following formula:

Total mEq = (30 X N_{HCl}) – (V_{NaOH} X N_{NaOH})

N_{HCl} = Normality of HCl volumetric solution.

V_{NaOH} = Volume of NaOH volumetric solution used for titration.

N_{NaOH} = Normality of NaOH volumetric solution.

2.3. In-vitro dissolution study

Reagents**:** Sodium Acetate Trihydrate (AR grade), Acetonitrile (HPLC grade), Methanol (HPLC grade), Triethylamine (AR grade), Acetic Acid (AR grade), Potassium Dihydrogen Phosphate (AR grade), Sodium Hydroxide (AR grade), Water (Milli-Q).

Equipment: Magnetic stirrer, Calibrated pH meter, Motor and Pestle, Burette.

Dosage forms: Aceproxyvon tablets, manufactured by Dr. Reddy's formulation, were compared against a reference Aceclofenac and Paracetamol fixed-dose combination formulation available in the market. These samples were properly checked for their batch number, manufacturing date, and expiration date before the study. The labelled active ingredients were Aceclofenac 100 mg and Paracetamol 325 mg.

In a discriminatory and biorelevant dissolution medium

A discriminatory and biorelevant dissolution system able to simulate the conditions of the human GIT in terms of dosing conditions and therapeutic objectives was selected. Since NSAIDs are recommended to be administered after meals and typical pH values measured soon after food intake range from 4-4.5, a 4.5 acetate buffer medium that reflects the GI conditions that are relevant to drug release from this formulation was selected. Further, with respect to the volume of the medium, gastric juice secretion is usually low in the fasted state, with the result that the volume of fluid available to dissolve the dose is much lower than the standard dissolution test volume of 900 ml. In this study, the dissolution parameters were: Dissolution Medium- (1000 ml), pH 6.5 Phosphate buffer, and 1000 ml pH 4.5 Acetate Buffer. Dissolution Apparatus: USP apparatus 1 (Basket) RPM: 100, temperature of dissolution medium: 37±0.5°C.

Preparation of dilute acetic acid: Dilute 10 mL of acetic acid to 100 mL with water and mix.

2.3.1. Preparation of dissolution medium

Preparation of pH 4.5 Acetate buffer:

2.9 g of sodium acetate trihydrate was dissolved in 900 ml of water. 14 ml of 2N acetic acid was added and diluted to mark 1000 ml with water. If necessary, pH was adjusted to 4.5 ± 0.05 with dilute acetic acid or 2N NaOH.

2.3.2. Preparation of buffer pH 6.5

Dissolve 13.6 g sodium acetate trihydrate in 1000 mL of water, add 2 mL triethylamine, and mix. Adjust the pH to 6.5± 0.05 with acetic acid, and mix. Filter the solution with a 0.45μ membrane filter.

Preparation of the Mobile phase: Prepare a mixture of buffer pH 6.5, acetonitrile: methanol in the ratio of 60:30:10 v/v/v, and degas.

Preparation of pH 6.8 phosphate buffer: Mix 250 mL of 0.2M potassium dihydrogen phosphate and 112 mL of 0.2M sodium hydroxide, and dilute to 1000 mL with water, and mix.

Preparation of pH 7.5 phosphate buffer: Dissolve 6.8 g of potassium dihydrogen phosphate and 1.7 g of NaOH in 1000 mL of water and mix. Adjust the pH to 7.50 ± 0.05 with a 0.2N NaOH solution or Orthophosphoric acid.

Preparation of Standard Solution: Accurately weigh and transfer 28 mg of Aceclofenac and 90 mg of Paracetamol working standard into a 50 mL volumetric flask. Add 5 mL methanol, sonicate to dissolve, dilute up to the mark with dissolution medium, and mix. Dilute 5 mL of this solution to 25 mL with dissolution medium and mix.

Preparation of the sample solution: The test was performed on 12 tablets. 1 tablet was placed in each basket and lowered down into the vessel containing 900 ml of dissolution medium, which is maintained at 37^o C ± 0.5^{o}C. 10 ml of aliquot was withdrawn from each vessel and filtered through a 0.45 μm nylon filter after discarding the first 3 ml of the filtrate.

The test procedure for dissolution testing: 1 injection filled with dissolution medium acts as a blank; 5 injections of standard solution; 1 injection of sample solution; chromatograms were recorded and an analyte peak was measured.

3. Results

Due to variations in formulations and manufacturing, drug dissolution profiles may differ, but these variations must not compromise product bioequivalence. To provide a graphical representation of the data, the in vitro release data (cumulative percent drug release) have been plotted against time. The actual drug content of the test tablets, as determined by the assay findings, is the basis for all dissolution data. The release profiles of different brands of Aceclofenac and Paracetamol fixed-dose tablets were shown in Tables 1 and 2 and Figures 1, 2 and 3. The ANC of Test product versus reference products is shown in Table 1.

Based on the results, ANC was found to be between 6-8 for Brand A, B, and C formulations. The ANC of brand A was found to be higher as compared to other competitor brands. For Brand D Formulation, the ANC was found to be

Table 1: Acid -neutralizing capacity

Manuf acturer	Batch No	mEq Results per gram (g)				
		Result 1	Result 2	Result 3	Mean	% RSD
Brand A	D2200167	7.53	7.39	7.34	7.42	1.32
Brand B	K2201122	6.62	6.84	6.76	6.74	1.64
Brand C	FRW571013A19	7.09	7.18	7.26	7.18	1.19
Brand D	2118146E	15.86	16.04	15.92	15.94	0.58

15.9. The difference in ANC with Brand C formulation is due to a change in formulation, as it is exclusively an antacid (Chewable tablet).

It was observed that the mean ANC of brands A, B, and C was 7.42, 6.74, and 7.18 mEq respectively. The mean ANC of the Brand D formulation was 15.9 mEq. Given the change in active component and excipient, it was observed that the mean ANC of Brand A, B, and C was lower than that of Brand D. When compared to other reference formulations, the ANC for Brand A was higher.

4. *In Vitro* Dissolution Study

4.1. Drug release of brands A, B and C at different intervals in pH 7.5 phosphate buffer

In 30 minutes, the mean drug (Brand A) release rate for Paracetamol 325 mg was found to be 97.7%. The maximum amount of drug was released in 20 minutes. In parallel, the mean amount of drug released for Aceclofenac 100 mg was found to be 98.6% in 30 minutes. The maximum amount of drug was released in 20 minutes (pH 7.5 phosphate buffer).

At 5, 10, 20, and 30 minutes, the mean % of drug (Brand A) release for Paracetamol was 40.3, 72.3, 97.2, and 97.7%. Whereas, for Aceclofenac, it was 37.1, 70.6, 97.6, and 98.6%. Paracetamol and Aceclofenac both showed maximum drug release at 20 minutes (pH 7.5 phosphate buffer).

The mean drug (Brand B) released in 30 minutes for Paracetamol 325 mg was found to be 98.1%. The maximum amount of drug is released in 20 minutes. Similarly, the average drug release rate for Aceclofenac 100 mg was found to be 100.6% in 30 minutes. The maximum amount of drug released was discovered in 10 minutes.

It was observed that the mean % of drug (Brand B) release of Paracetamol at 5, 10, 20, and 30 minutes was 82.6, 93.7, 97.0, and 98.1% respectively and 94.8, 99.8, 100.5, and 100.6% respectively for Aceclofenac. The maximum drug release of Paracetamol was found at 20 minutes and that of Aceclofenac was at 10 minutes.

The mean drug (Brand C) released in 30 minutes for Paracetamol 325 mg was found to be 99.2%. The maximum amount of drug is released in 10 minutes. Similarly, the average drug release rate for Aceclofenac 100 mg was found to be 97.1% in 30 minutes. The maximum amount of drug released was discovered in 10 minutes.

At 5, 10, 20, and 30 minutes, the mean % of drug (Brand C) release for Paracetamol was 91.2, 97.7, 98.5, and 99.2%, and for Aceclofenac, 94.6, 98.3, 98.6, and 97.1%, respectively. Aceclofenac and Paracetamol both had a maximum drug release time of 10 minutes.

The Mean % of drug released for Paracetamol was more than 97% in 30 minutes in all formulations. Drug release was found to be slower in Brand A tablets as compared to Brand B and C at the initial time point. The % Mean drug released for Aceclofenac was found to be more than 97% in 30 minutes in all the formulations. Drug release was found to be slower in Brand A tablets as compared to Brand B and C at the initial time point. (pH 7.5 phosphate buffer).

4.2. Drug release of brands A, B and C at different intervals in pH 6.8 phosphate buffer.

The Mean % drug (Brand A) release of Paracetamol at 5, 10, 20, and 30 minutes was 43.3, 76.6, 96.0, and 97.5%, for Aceclofenac it was 37.1, 70.3, 94.5 and 98.2% respectively. The maximum drug release of Paracetamol was seen at 20 minutes and Aceclofenac was seen at 10 minutes (pH 6.8 phosphate buffer).

The % mean of the drug (Brand A) release for Paracetamol was determined to be 97.5% in 30 minutes. The maximum drug released was found to be in 20 minutes. In 30 minutes % mean drug release of Aceclofenac was 98.2%. The maximum drug was released in 20 minutes. (pH 6.8 phosphate buffer).

The mean drug (Brand B) released in 30 minutes for Paracetamol was found to be 98.3%. The maximum amount of drug is released in 10 minutes. Similarly, the average drug release rate for Aceclofenac was found to be 99.2% in 30 minutes. The maximum amount of drug released was discovered in 10 minutes (pH 6.8 phosphate buffer).

At 5, 10, 20, and 30 minutes, the mean% of the drug (Brand B) release for Paracetamol was 81.6, 94.0, 97.5, and 98.3%, and for Aceclofenac, it was 85.1, 95.6, 98.2%, and 99.2%, respectively. Both Paracetamol and Aceclofenac showed maximum drug release at 10 minutes (pH 6.8 phosphate buffer).

The Mean % of drug (Brand C) release of Paracetamol at 5, 10, 20, and 30 minutes was 72.1, 88.5, 94.6, and 96.4% respectively and for Aceclofenac, it was 79.2, 94.3, 97.2, and 98.1% respectively. The maximum drug release of Paracetamol was found to be at 20 minutes, whereas that of Aceclofenac was at 10 minutes. (pH 6.8 phosphate buffer).

The % Mean drug release for Paracetamol was found to be more than 96% in 30 minutes in all formulations. Drug release was found to be slower in Brand A tablets as compared to Brand B and C in the initial time point. % Mean

drug released for Aceclofenac was found to be more than 98% in 30 minutes in all the formulations. Drug release was found to be slower in Brand A tablets as compared to Brand B and C in the initial time point. (pH 6.8 phosphate buffer).

4.3. Drug release of Brand A, B and C at different intervals in pH 4.5 acetate buffer

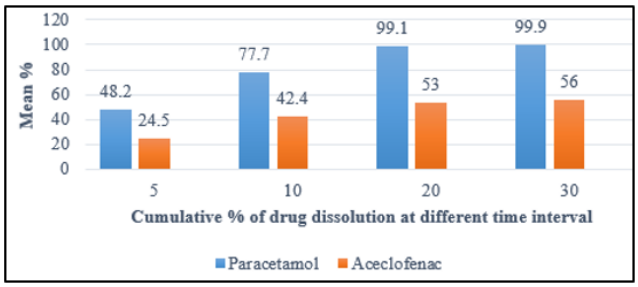

Fig. 1: Cumulative % drug dissolution of test product- Brand A (Paracetamol 325mg and aceclofenac 100mg) tablets in pH 4.5, acetate buffer

From Figure 1 it was revealed that, at 5, 10, 20, and 30 minutes, the mean % of drug (Brand A) release for Paracetamol was 48.2, 77.7, 99.1, 99.9% and it was 24.5, 42.4, 53.0 and 56.0% respectively, for Aceclofenac. Paracetamol showed maximum drug release at 20 minutes.

It was observed that % mean drug released for Paracetamol was found to be 99.9% in 30 minutes. The maximum drug released was found to be in 20 minutes. Similarly, % mean drug released for Aceclofenac was found to be 56.0% in 30 minutes.

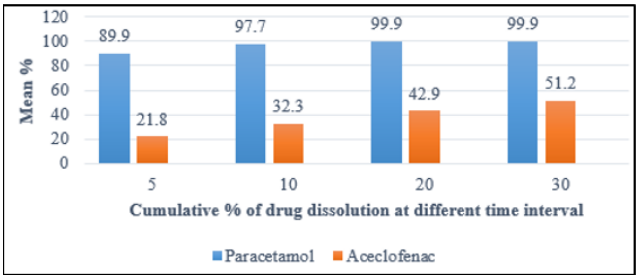

Fig. 2: Cumulative % drug dissolution of reference product- Brand B (Paracetamol 325mg and Aceclofenac 100mg) Tablets at different time intervals

From Figure 2 it was revealed that, at 5, 10, 20, and 30 minutes, the mean % of drug (Brand B) release for Paracetamol was 89.9, 97.7, 99.9, 99.9% and for Aceclofenac, it was 21.8, 32.3, 42.9, and 51.2% respectively. Paracetamol showed maximum drug release in 10 minutes.

It was found that the % Mean drug released for Paracetamol was 99.9% in 30 minutes. The maximum drug was released in 10 minutes. % Mean drug released for Aceclofenac was 51.2% in 30 minutes.

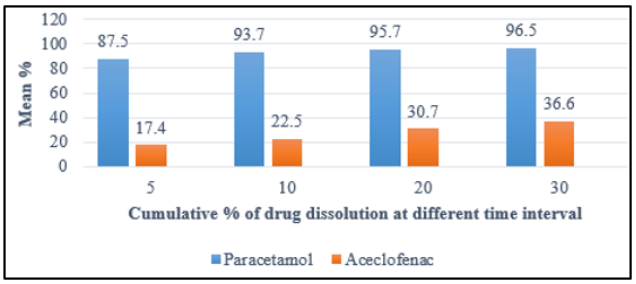

Fig. 3: Cumulative % drug dissolution of reference product- Brand C (Paracetamol 325mg and Aceclofenac 100mg) tablets in ph 4.5, acetate buffer

From Figure 3 it was revealed that, the mean % of drug (Brand C) release of Paracetamol at 5, 10, 20, and 30 minutes was 87.5, 93.7, 95.7, 96.5% and for Aceclofenac it was 17.4, 22.5, 30.7, and 36.6% respectively. The maximum drug release of Paracetamol was seen at 10 minutes.

It was observed that the % Mean drug released for Paracetamol was found to be 96.5% in 30 minutes. The maximum drug released was found to be in 10 minutes. % Mean drug released for Aceclofenac was found to be 36.6% in 30 minutes.

From the above study, it was concluded that the % mean drug released for Paracetamol was found to be more than 99% in 30 minutes in Brand A and B formulations as compared to Brand C (96.5%). Drug release was found to be slower in Brand A tablets as compared to Brand B and C in the initial time point. The % mean drug released for Aceclofenac was on the lower side for all manufacturers. However, the release is more in Brand A formulation as compared to Brand B and C formulation.

Table 2: Mean % of drug released after 30 minutes in all the pH

Manufacturer Name	Media	Mean % of drug release after 30 minutes	
		Paracetamol	Aceclofenac
Brand A	pH	97.7	98.6
Brand B	7.5Phosphate	98.1	100.9
Brand C	buffer	99.2	97.1
Brand A	pH 6.8	97.5	98.2
Brand B	Phosphate	98.3	99.2
Brand C	buffer	96.4	98.1
Brand A	pH 4.5	99.9	56.0
Brand B	Acetate	99.9	51.2
Brand C	Buffer	96.5	36.6

At pH 7.5 Phosphate Buffer, the mean percentage of drug release rate after 30 minutes for Brand B formulation of Paracetamol (98.1%) and Aceclofenac (100.9%). The mean percentage of drug release rate after 30 minutes for Brand C formulation of Paracetamol (99.2%) and Aceclofenac

(97.1%). The mean percentage of drug release rate after 30 minutes for Brand A formulation of Paracetamol (97.7%) and Aceclofenac (98.6%).

At pH 6.8 Phosphate Buffer, the mean percentage of drug release rate after 30 minutes for Brand B formulation of Paracetamol (98.3%) and Aceclofenac (99.2%). The mean percentage of drug release rate after 30 minutes for Brand C formulation of Paracetamol (96.4%) and Aceclofenac (98.1%). The mean percentage of drug release rate after 30 minutes for Brand A formulation of Paracetamol (97.5%) and Aceclofenac (98.2%).

At pH 4.5 Acetate Buffer, the mean percentage of drug release rate after 30 minutes for Brand B formulation of Paracetamol (99.9%) and Aceclofenac (51.2%). The mean percentage of drug release rate after 30 minutes for Brand C formulation of Paracetamol (96.5%) and Aceclofenac (36.6%). The mean percentage of drug release rate after 30 minutes for Brand A formulation of Paracetamol (99.9%) and Aceclofenac (56.0%) (Table 2).

5. Discussion

Drug dissolution testing and ANC testing are qualitative and quantitative analytical techniques for assessing the quality of pharmaceutical products, which eventually increases therapeutic efficacy. Thus, in-vitro evaluation of novel drugs becomes useful and necessary.

Sunil Agarwal et al. (2019) demonstrated a comparative in vitro dissolution study and reported that the mean percentage of drug release of Aceclofenac and Paracetamol in pH 4.5 Acetate buffer after 30 minutes was 64% and 88%.[10] Similarly, the mean % of drug release of Aceclofenac and Paracetamol in pH 4.5 acetate buffer after 30 minutes in the present study was 56.0% and 99.9%. The mean drug dissolution rate was high after 30 minutes for both Paracetamol and Aceclofenac in all pH media.

S. M. Ashraful Islam et al. (2011) conducted a comparative in vitro dissolution study and stated that 80% of Aceclofenac was released after 30 minutes in a pH 6.8 phosphate buffer.[3] In the present study, 98.2% of Aceclofenac was released after 30 minutes in a pH 6.8 phosphate buffer.

M. E. M. Hassouna et al. (2012) performed a comparative in vitro dissolution study and demonstrated that 90.82% of Paracetamol was released after 30 minutes in pH 6.8 phosphate buffer.[13] Parallel to this, the present study results showed that 98.2% of Paracetamol was released after 30 minutes in a pH 6.8 phosphate buffer.

Anil Kumar Shinde et al. (2019) conducted a study, and the results revealed that 71.9% of Paracetamol was released after 30 minutes in pH 7.5 phosphate buffer.[14] The present study results showed that 97.7% of Paracetamol was released after 30 minutes in pH 7.5 phosphate buffer.

Jahan Nur Rahman Hazarika et al. (2017) performed a study and stated that around 59- 76% of Aceclofenac was released from all the products used in the study after 30 minutes in pH 7.5 phosphate buffer.[15] In contrast to the above, the present study demonstrated that 98.6% of Aceclofenac was released after 30 minutes in pH 7.5 phosphate buffer.

In a study conducted by Mary E. MacCara et al. (1985), the ANC of Gelusil tablets was 11.4 mEq.[16] In contrast to the above, the present study results revealed that the ANC of Gelusil tablets was 15.92 mEq.

Drug solubility, rate of dissolution, and gastrointestinal permeability are fundamental parameters that control the rate and extent of drug absorption and its bioavailability.[17,18]The rate of dissolution is directly proportional to bioavailability.[19] Analgesics with a high ANC are required for the efficient management of gastrointestinal permeability. Therefore, higher ANC and better dissolution can help in better bioavailability.

6. Conclusion

The ANC for Brand A formulation was higher (7.42 mEq /g) compared to Brand B formulation (6.74 mEq /g) and Brand C formulation (7.18 mEq/g). The reference antacid, ANC was 15.9 mEq/g as it is exclusively an antacid tablet. The mean drug release rate for Paracetamol was comparable after 30 minutes in all formulations by using three different media. The mean drug release rate for Aceclofenac was comparable after 30 minutes in all formulations by using pH 6.8 and pH 7.5 phosphate media. However, the mean drug release rate for Aceclofenac was found to be higher in the test product as compared to Brand B and C in 30 minutes by using pH 4.5 acetate media.

Based on study results, it was concluded that novel Brand A showed faster dissolution and higher acid-neutralizing capacity as compared to reference products. This enhancement in dissolution rate may further result in a rapid onset of action and better therapeutic efficacy.

7. Source of Funding

None.

8. Conflict of Interest

None.

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