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# Comparative dissolution study in different pH conditions of Bilastine Tablet

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***Abstract – The rate of drug release of a solid dosage form through different periods can be assessed using disintegrating studies. In this study, we aimed to compare 2 bilastine tablets available in Bangladeshi market. Three different buffer media are utilised, having pH 1.2, 4.5 and 6.8 respectively. The HPLC parameters are as follows: mobile phase, buffer: acetonitrile (pH 4.0), 6.5:3.5; column, Kromasil C18 (150 mm X 4.6 mm, and 5µm); detection at a wavelength of 207 nm with the temperature set at an oven temperature of 25°C and flow rate was kept at 1 mL/min using PDA detector. The similarity factor of the type a bilastine tablets (at pH 1.2) is 83.27 and for type B bilastine tablets (at pH 1.2), difference factor is 1.01. Both of these requirements are fulfilled by the USP standard. But in other conditions pH 4.6 and 6.8 not same. These result show that the dissolution profile of B category tablet is not suitable formulation further in vivo test is require for the justification the plasma profile level at different time interval.***

***Keywords – RP-HPLC, Dissolution, Bilastine, Similarity factor, Difference factor.***

## I. INTRODUCTION

Tablet is a most common form of solid dosage form. It has many advantages over the other dosage form like liquid or semisolid. The solid dosage form such as tablet, capsule form drug release depends on the formulation form of the dosage form and its physiochemical nature of the molecule [1]. The formulation can enhance the dissolution process by adding different types of excipient with the active pharmaceutical ingredients. When the drug product release from the drug product the next step is drug absorption. Lipophilic drugs are more bio permeability properties than the hydrophilic drugs. So there is BCS drug category that indicate the how any drug nature in the physical, chemical and the attributes with the body permeability [2]. The dissolution test ensures any drug how fast release from its dosage form. If the drug molecules release from the product than it easily has the chance to go its active site of action by absorption process. When the inventor company make a dosage form the other market company also make same tablet but there is needed to the bioequivalence study to approve the pharmaceutical guideline.

The dissolution profile is one of the major parameter to pass this approval. The difference factor $f_1$ and similarity factor $f_2$ result also needed for support this data. The difference factor (f1) and the similarity factor (f2) are used to compare the dissolution profiles of a test formulation with that of a standard product [3]. These factors help to detect whether two dissolution curves are sufficiently close to one another, which is important in dosage form development and regulatory submissions [4]. The percentage of inaccuracy between the two profiles at each time point is measured by the difference factor (f1). This indicates how different the test and standard products are in terms of the quantity of medication dissolved. According to previous research [5], a low f1 number (between 0 and 15) suggests that the two medication profiles are quite similar. The medication formulations could not be comparable if the f1 value is high, as it indicates a larger variance. Both profiles are comparable and may be thought of as interchangeable if the f2 value is in the 50–100 range. A substantial change in the dissolving behavior of the dosage form is indicated by values below 50 [6].

Anxieties are often treated with bilastine, a second-generation antihistamine [7]. Allergic reactions are alleviated because it inhibits peripheral H1-histamine receptors. Patients requiring alertness for everyday tasks may find bilastine useful since it has less penetration across the blood-brain barrier and considerably fewer effects on the central nervous system compared to first-generation antihistamines. After being taken orally, the medication is absorbed quickly and reaches its peak plasma concentrations in about an hour to two hours [8].

Bilastine has a relatively long half-life, allowing once-daily dosing without significant accumulation. It has a limited hepatic metabolism and a low potential for interactions with other drugs. These characteristics make it a preferable option for individuals with hepatic impairment or those receiving multiple medications. Clinically, bilastine is indicated for the treatment of seasonal and perennial allergic rhinitis as well as chronic spontaneous urticaria. Its efficacy in relieving nasal congestion, itching, and skin wheals has been well documented. The medication is generally well tolerated, with adverse effects such as headache or mild drowsiness occurring rarely [9].

## II. METHODS AND MATERIALS

### *2.1 Materials information*

Bilastine 20 mg tablet of A category pharmaceutical and B category pharmaceutical were sold from the local market of Bangladesh. Where A is from the top ten company of Bangladesh and B is in the from twenty to thirty ranking company. The chemicals from Merck, Germany, included acetonitrile, formic acid, triethylamine, hydrochloric acid, sodium acetate trihydrate, acetic acid, sodium hydroxide, and potassium dihydrogen phosphate.

Mix 8.5 mL of hydrochloric acid with 500 mL of filtered water, and then add 1000 mL to make the dissolution medium (0.1 N HCl pH 1.2).

The dissolving agent, an acetate buffer with a pH of 4.5, is prepared by mixing 2.99 g of sodium acetate trihydrate with 14 mL of acetic acid to a final volume of 1000 mL.

Mix 6.8 grams of potassium dihydrogen phosphate with 0.896 grams of sodium hydroxide in up to 1000 milliliters of water to make the dissolution media (phosphate buffer pH 6.8).

The mobile phase consisted of a 65:35 (v/v) mixture of buffer acetonitrile and other components. Pass through a 0.45 µ membrane filter for filtration.

Various dissolving media were used as diluents to create a diluted solution.

### *2.2 Commonly used methods of readiness*

Volumetric flask with 100 mL of Bilastine working standard containing 42 mg. Stir in 40 mL of dissolving medium and shake well to dissolve. Then, sonicate for 10 minutes with 0.1 N HCl and 60 minutes with acetate and phosphate buffers at pH 4.5 and 6.8, respectively, while shaking in between. Gradually add the dissolving agent and stir until well combined. Fill a clean 100 mL volumetric flask to capacity with dissolving media, then transfer 5 mL of this solution and stir well. Pass the sample through a 0.45µ-disc filter according to references [10,11,12].

The Auto sampler and PDA detector are part of the SHIMADZU Prominence HPLC system. Volume of 900 mL using various dissolving media and the USP-II device (paddle). With a temperature of 37°C ± 0.5°C and a stirring speed of 50 rpm. The intervals of 5, 10, 15, 20, 30, and 45 minutes follow. Kromasil C18, measuring 4.6 mm x 150 mm and 5 µm, was used as the column for the technique. At 1.0 mL/min, the flow rate was calibrated. A volume of 20 mL was injected using a wavelength of 207 nm as chosen for the procedure. The column oven did not have a set temperature.

## III. RESULTS

TABLE-1: CUMULATIVE PERCENT RELEASE TABLET OF A CATEGORY PHARMACEUTICAL IN 0.1 N HCL PH 1.2

| Tablet no | 5 mins | 10 mins | 15 mins | 20 mins | 30 mins | 45 mins | 60 mins |
|---|---|---|---|---|---|---|---|
| 1 | 97 | 98 | 99 | 99 | 101 | 97 | 95 |
| 2 | 99 | 99 | 99 | 99 | 100 | 97 | 94 |
| 3 | 97 | 99 | 99 | 99 | 99 | 97 | 94 |
| 4 | 99 | 99 | 100 | 99 | 100 | 97 | 95 |
| 5 | 99 | 99 | 100 | 99 | 101 | 97 | 95 |
| 6 | 99 | 100 | 99 | 100 | 101 | 98 | 96 |
| 7 | 99 | 100 | 100 | 100 | 101 | 98 | 96 |
| 8 | 99 | 100 | 100 | 100 | 101 | 99 | 96 |
| 9 | 99 | 100 | 100 | 99 | 100 | 97 | 96 |
| 10 | 100 | 100 | 95 | 99 | 100 | 98 | 96 |
| 11 | 100 | 100 | 100 | 100 | 101 | 99 | 96 |
| 12 | 100 | 100 | 101 | 100 | 101 | 99 | 96 |
| **Mean** | **99** | **100** | **100** | **100** | **100** | **98** | **96** |
| STDEV | 1.00 | 0.68 | 1.59 | 0.51 | 0.67 | 0.87 | 0.79 |
| RSD (%) | 1.006 | 0.678 | 1.597 | 0.515 | 0.674 | 0.882 | 0.829 |

TABLE-2: CUMULATIVE PERCENT RELEASE TABLET OF B CATEGORY PHARMACEUTICAL IN 0.1 N HCL PH 1.2

| Tablet no | 5 mins | 10 mins | 15 mins | 20 mins | 30 mins | 45 mins | 60 mins |
|---|---|---|---|---|---|---|---|
| 1 | 98 | 100 | 99 | 98 | 98 | 97 | 94 |
| 2 | 97 | 98 | 97 | 97 | 97 | 96 | 95 |
| 3 | 103 | 99 | 99 | 99 | 99 | 97 | 96 |
| 4 | 100 | 97 | 97 | 96 | 95 | 95 | 95 |
| 5 | 101 | 99 | 99 | 98 | 97 | 96 | 93 |
| 6 | 99 | 101 | 100 | 100 | 101 | 98 | 93 |
| 7 | 101 | 99 | 99 | 97 | 98 | 97 | 96 |
| 8 | 104 | 101 | 101 | 100 | 98 | 97 | 97 |
| 9 | 100 | 99 | 102 | 101 | 100 | 98 | 95 |
| 10 | 99 | 103 | 96 | 100 | 99 | 98 | 98 |
| 11 | 99 | 103 | 103 | 102 | 102 | 97 | 95 |
| 12 | 99 | 101 | 99 | 98 | 98 | 99 | 96 |
| **Mean** | **100** | **100** | **100** | **98** | **98** | **97** | **95** |
| STDEV | 2.00 | 1.86 | 2.11 | 1.80 | 1.88 | 1.08 | 1.48 |
| RSD (%) | 2.000 | 1.859 | 2.119 | 1.831 | 1.920 | 1.112 | 1.556 |

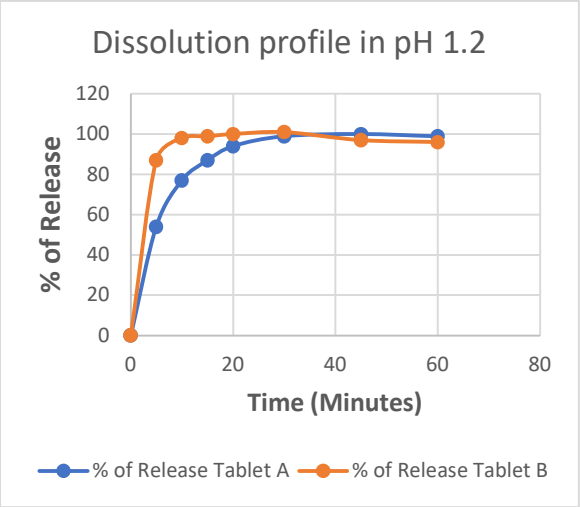


Figure1: Comparative dissolution profile in pH 1.2

TABLE-3: CUMULATIVE PERCENT RELEASE TABLET OF A CATEGORY PHARMACEUTICAL IN ACETATE BUFFER PH 4.5

| Tablet no | 5 mins | 10 mins | 15 mins | 20 mins | 30 mins | 45 mins | 60 mins |
|---|---|---|---|---|---|---|---|
| 1 | 68 | 88 | 98 | 100 | 101 | 99 | 97 |
| 2 | 75 | 94 | 97 | 100 | 101 | 99 | 97 |
| 3 | 69 | 89 | 100 | 101 | 101 | 100 | 98 |
| 4 | 76 | 95 | 100 | 102 | 102 | 100 | 99 |
| 5 | 74 | 95 | 100 | 101 | 102 | 100 | 98 |
| 6 | 73 | 94 | 99 | 100 | 101 | 99 | 96 |
| 7 | 78 | 95 | 99 | 100 | 101 | 98 | 97 |
| 8 | 79 | 94 | 99 | 99 | 100 | 98 | 97 |
| 9 | 77 | 94 | 99 | 100 | 101 | 100 | 99 |
| 10 | 78 | 95 | 96 | 101 | 103 | 101 | 98 |
| 11 | 80 | 95 | 98 | 100 | 100 | 98 | 98 |
| 12 | 80 | 94 | 99 | 99 | 100 | 98 | 88 |
| Mean | **76** | **93** | **98** | **100** | **101** | **99** | **97** |
| STDEV | 3.99 | 2.39 | 1.18 | 0.87 | 0.90 | 1.03 | 2.92 |
| RSD (%) | 5.247 | 2.570 | 1.199 | 0.865 | 0.891 | 1.035 | 3.005 |

TABLE-4: CUMULATIVE PERCENT RELEASE TABLET OF B CATEGORY PHARMACEUTICAL IN ACETATE BUFFER PH 4.5

| Tablet no | 5 mins | 10 mins | 15 mins | 20 mins | 30 mins | 45 mins | 60 mins |
|---|---|---|---|---|---|---|---|
| 1 | 93 | 99 | 100 | 99 | 100 | 98 | 96 |
| 2 | 95 | 98 | 98 | 98 | 99 | 96 | 93 |
| 3 | 94 | 99 | 99 | 99 | 100 | 97 | 94 |
| 4 | 95 | 98 | 97 | 97 | 97 | 96 | 94 |
| 5 | 97 | 99 | 99 | 98 | 99 | 97 | 93 |
| 6 | 101 | 101 | 101 | 100 | 101 | 98 | 93 |
| 7 | 98 | 100 | 100 | 99 | 100 | 96 | 96 |
| 8 | 101 | 103 | 102 | 101 | 102 | 99 | 97 |
| 9 | 99 | 102 | 101 | 99 | 102 | 99 | 97 |
| 10 | 100 | 102 | 96 | 101 | 102 | 99 | 97 |
| 11 | 101 | 102 | 102 | 102 | 101 | 99 | 97 |
| 12 | 104 | 101 | 101 | 101 | 102 | 99 | 96 |
| Mean | **98** | **101** | **100** | **100** | **100** | **98** | **95** |
| STDEV | 3.41 | 1.74 | 1.99 | 1.51 | 1.56 | 1.29 | 1.71 |
| RSD (%) | 3.476 | 1.733 | 1.986 | 1.508 | 1.564 | 1.312 | 1.793 |

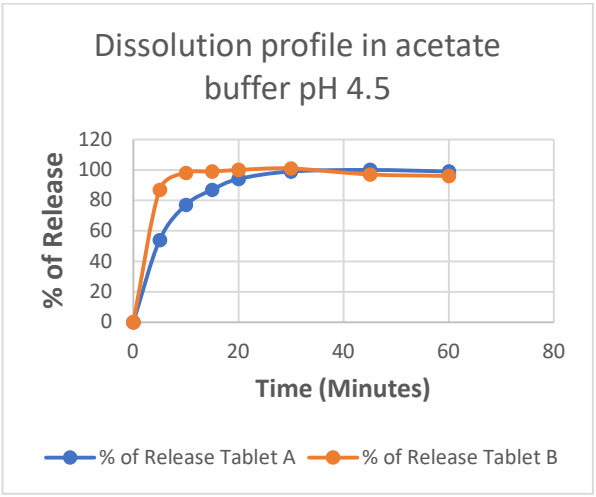


**Figure 2: Comparative dissolution profile in pH 4.5**

TABLE-5: CUMULATIVE PERCENT RELEASE TABLET OF A CATEGORY PHARMACEUTICAL IN PHOSPHATE BUFFER PH 6.8

| Tablet no | 5 mins | 10 mins | 15 mins | 20 mins | 30 mins | 45 mins | 60 mins |
|---|---|---|---|---|---|---|---|
| 1 | 65 | 76 | 88 | 95 | 98 | 100 | 100 |
| 2 | 52 | 78 | 89 | 94 | 99 | 99 | 99 |
| 3 | 53 | 76 | 88 | 93 | 98 | 100 | 99 |
| 4 | 53 | 76 | 88 | 93 | 99 | 101 | 98 |
| 5 | 50 | 76 | 87 | 93 | 100 | 100 | 98 |
| 6 | 49 | 78 | 87 | 94 | 100 | 101 | 98 |
| 7 | 54 | 78 | 85 | 93 | 100 | 101 | 100 |
| 8 | 55 | 76 | 88 | 94 | 98 | 99 | 100 |
| 9 | 55 | 76 | 87 | 95 | 100 | 100 | 99 |
| 10 | 55 | 79 | 87 | 94 | 99 | 100 | 100 |
| 11 | 56 | 76 | 89 | 94 | 99 | 101 | 99 |
| 12 | 56 | 75 | 88 | 94 | 99 | 101 | 99 |
| **Mean** | **54** | **77** | **87** | **94** | **99** | **100** | **99** |
| STDEV | 4.01 | 1.22 | 1.08 | 0.72 | 0.79 | 0.75 | 0.79 |
| RSD (%) | 7.427 | 1.588 | 1.233 | 0.767 | 0.802 | 0.755 | 0.801 |

TABLE-6: CUMULATIVE PERCENT RELEASE TABLET OF B CATEGORY PHARMACEUTICAL IN PHOSPHATE BUFFER PH 6.8

| Tablet no | 5 mins | 10 mins | 15 mins | 20 mins | 30 mins | 45 mins | 60 mins |
|---|---|---|---|---|---|---|---|
| 1 | 81 | 98 | 100 | 100 | 101 | 97 | 96 |
| 2 | 85 | 97 | 99 | 100 | 100 | 97 | 94 |
| 3 | 82 | 98 | 100 | 101 | 101 | 97 | 95 |
| 4 | 85 | 97 | 99 | 100 | 100 | 96 | 94 |
| 5 | 88 | 99 | 101 | 102 | 102 | 96 | 93 |
| 6 | 89 | 97 | 99 | 100 | 104 | 98 | 93 |
| 7 | 89 | 100 | 102 | 103 | 100 | 100 | 97 |
| 8 | 88 | 97 | 98 | 99 | 98 | 97 | 98 |
| 9 | 88 | 96 | 98 | 99 | 99 | 95 | 97 |
| 10 | 91 | 98 | 95 | 100 | 99 | 95 | 97 |
| 11 | 89 | 96 | 98 | 99 | 100 | 96 | 98 |
| 12 | 92 | 98 | 99 | 100 | 100 | 97 | 97 |
| Mean | **87** | **98** | **99** | **100** | **101** | **97** | **96** |
| STDEV | 3.36 | 1.16 | 1.77 | 1.22 | 1.56 | 1.36 | 1.86 |
| RSD (%) | 3.863 | 1.189 | 1.789 | 1.210 | 1.548 | 1.397 | 1.943 |

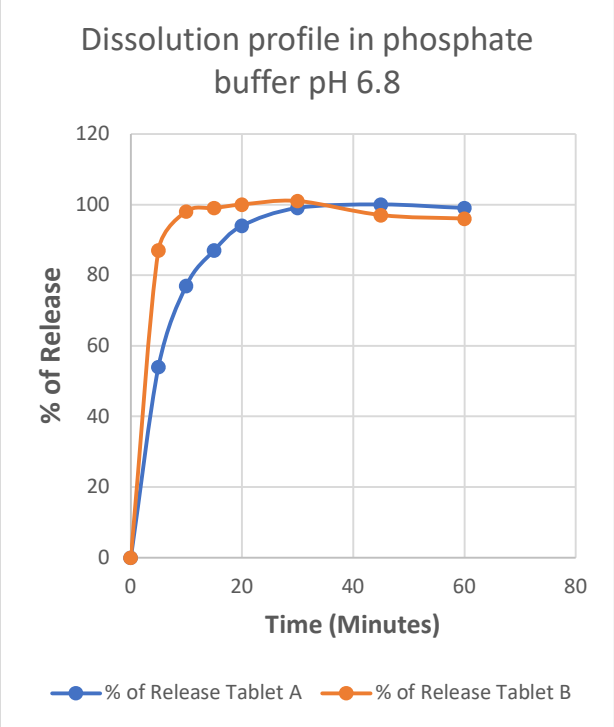


Figure 3: Comparative dissolution profile in pH 6.8

The dissolution profile data were also compared mathematically using the similarity factor $f_2$ and difference factor $f_1$, which is calculated by the following equation.

$$f_2 = 50 \times \log \{[1 + (1/n) \Sigma_{t=1}^{n} (R_t - T_t)^2]^{-0.5} \times 100\}$$

$$f_1 = \{[\Sigma_{t=1}^{n} |R_t - T_t|] / [\Sigma_{t=1}^{n} R_t]\} \times 100$$

TABLE-7: SIMILARITY FACTOR F2 AND DIFFERENCE FACTOR F1 FOR DISSOLUTION MEDIUM OF 0.1 N HCL

| Time (min) | $R_t$ (Tablet A) | $T_t$ (Tablet | $(R_t-T_t)$ | $(R_t-T_t)^2$ |
|---|---|---|---|---|
| 5 | 99 | 100 | 1 | 1 |
| 10 | 100 | 100 | 0 | 0 |
| 15 | 100 | 100 | 0 | 0 |
| 20 | 100 | 98 | 2 | 4 |
| 30 | 100 | 98 | 2 | 4 |
| 45 | 98 | 97 | 1 | 1 |
| 60 | 96 | 95 | 1 | 1 |
| Sum $(R_t-T_t)$ | | | | 7 |
| Sum $(R_t-T_t)^2$ | | | | 11 |
| Sum $R_t$ | | | | 693 |
| Similarity factor f2 | | | | 83.27 |
| Difference factor f1 | | | | 1.01 |

TABLE-8: SIMILARITY FACTOR F2 AND DIFFERENCE FACTOR F1 FOR DISSOLUTION MEDIUM OF ACETATE BUFFER PH 4.5

| Time (min) | $R_t$ (Tablet A) | $T_t$ (Tablet B) | $(R_t-T_t)$ | $(R_t-T_t)^2$ |
|---|---|---|---|---|
| 5 | 76 | 98 | 22 | 484 |
| 10 | 93 | 101 | 8 | 64 |
| 15 | 98 | 100 | 2 | 4 |
| 20 | 100 | 100 | 0 | 0 |
| 30 | 101 | 100 | 1 | 1 |
| 45 | 99 | 98 | 1 | 1 |
| 60 | 97 | 95 | 2 | 4 |
| Sum $(R_t-T_t)$ | | | | 36 |
| Sum $(R_t-T_t)^2$ | | | | 558 |
| Sum $R_t$ | | | | 664 |
| Similarity factor f2 | | | | 43.20 |
| Difference factor f1 | | | | 5.42 |

TABLE-9: SIMILARITY FACTOR F2 AND DIFFERENCE FACTOR F1 FOR DISSOLUTION MEDIUM OF PHOSPHATE BUFFER PH 6.8

| Time (min) | $R_t$ (Tablet A) | $T_t$ (Tablet B) | $(R_t-T_t)$ | $(R_t-T_t)^2$ |
|---|---|---|---|---|
| 5 | 54 | 87 | 33 | 1089 |
| 10 | 77 | 98 | 21 | 441 |
| 15 | 87 | 99 | 12 | 144 |
| 20 | 94 | 100 | 6 | 36 |
| 30 | 99 | 101 | 2 | 4 |
| 45 | 100 | 97 | 3 | 9 |
| 60 | 99 | 96 | 3 | 9 |
| Sum $(R_t-T_t)$ | | | | 80 |
| Sum $(R_t-T_t)^2$ | | | | 1732 |
| Sum $R_t$ | | | | 610 |
| Similarity factor f2 | | | | 30.95 |
| Difference factor f1 | | | | 13.11 |

| Medium (50 rpm) | Difference factor f1 | Similarity factor f2 |
|---|---|---|
| pH 1.2 | 1.01 | 83.27 |
| pH 4.6 | 5.42 | 43.20 |
| pH 6.8 | 13.11 | 30.95 |

## IV. DISCUSSIONS

The dissolution study of two local marketed Bangladeshi pharmaceutical products, identified as Category A and Category B, show a notable difference in their release profiles across three dissolution media. In 0.1 N HCl (pH 1.2), both products exhibited similar rapid and complete drug release, with mean values approaching 100% within the first 15 minutes. It indicates the efficient disintegration and dissolution for both formulations under acidic conditions. The calculated similarity factor (f2 = 83.27) and difference factor (f1 = 1.01) confirm that the profiles are highly comparable, meeting regulatory criteria for product equivalence information.

In acetate buffer (pH 4.5), distinct variations are observed. Category A tablet displayed a slower initial release, particularly at the 5-minute interval, whereas Category B dissolved more rapidly and consistently over time. These differences are reflected in the lower similarity factor (f2 = 43.20), which falls below the acceptable threshold of 50, indicating a lack of profile similarity. On the other hand, the difference factor (f1 = 5.42) remains within the acceptable limit, suggesting moderate yet noteworthy deviation in the two formulations.

A major disparity was observed in phosphate buffer (pH 6.8). The similarity factor (f2 = 30.95) and difference factor (f1 = 13.11) confirm significant differences between the two formulations in this medium. These findings imply that formulation variables such as excipient uses that influencing dissolution behavior at neutral pH.

## V. CONCLUSION:

The comparative dissolution study reveals that the two Bangladeshi local marketed products perform similarly show in only under acidic conditions. In 0.1 N HCl (pH 1.2), both tablet category A and category B showed rapid and complete drug release, supported by an acceptable similarity factor and minimal difference. However, in acetate buffer (pH 4.5) and phosphate buffer (pH 6.8), notable discrepancies has been observed. Category B tablet consistently exhibited faster dissolution, while category A released the drug more slowly. The low f2 values in these media confirm the lack of profile similarity in dosage formulation. Finally, the two type tablet formulations are comparable in gastric conditions but differ significantly at higher pH conditions.

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