

# Acceptability and Effectivity of Four Feminine Wash Products in Maintaining the Physiologic Vaginal pH of Reproductive and Menopausal Age Women

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## ABSTRACT

**Objective.** To determine whether four (4) feminine hygiene wash products maintain normal vaginal pH and are acceptable among reproductive and menopausal age women.

**Methods.** A randomized, double blind, three-period, three-way crossover trial on 90 reproductive age women and 30 menopausal women measuring external and internal vaginal pH levels and product acceptability after using different feminine wash for 3 weeks.

**Results.** There were significant differences in mean change in internal vaginal pH values among the three feminine wash products ( $p=0.0392$ ) in the reproductive age group. Majority of the subjects expressed 'extreme satisfaction' on the different features of the products. In the menopausal age group, there was a statistically significant difference in mean pH change in the external genitalia ( $p=0.0279$ ). Feminine Wash 4 appeared to be most acceptable.

**Conclusion.** Using feminine wash may help maintain vaginal pH levels within the physiologic range thus prevents vaginal infections. Good acceptability of use among the subjects implies good compliance and therefore, a practice that can be adopted on a long-term basis as part of a woman's good hygienic practice.

*Key Words:* feminine hygiene products; genitalia, female; hydrogen-ion concentration, menopause, vagina/microbiology

## INTRODUCTION

The use of feminine wash has gained popularity recently. In the Philippines, there has been no clear evidence as to the advantage of its daily use. In a local study, the top three reasons why most women consider using feminine wash are (1) to have fresh-feeling after washing; (2) deodorizing effect; and (3) clean-feeling effect.<sup>1</sup>

Most feminine wash that are in the market have varied pH levels compared to what is physiologic in the vaginal area. The range of vaginal pH varies with age, and is known to be most acidic during puberty/reproductive age and pregnancy.<sup>2,3</sup> This acidity has been shown to be microbicidal for many sexually transmitted disease (STD) pathogens including HIV.<sup>2</sup>

According to the Center for Disease Control and Prevention, bacterial vaginosis (BV) is the most common cause of vaginal symptoms among women.<sup>4</sup> In BV, there is an overgrowth of a variety of mostly anaerobic bacteria and a reduction in lactobacilli, as well as a marked increase in vaginal pH to  $>4.5$ .<sup>2</sup>

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Cohen has identified that the optimal pH for growth of some common organisms are as follows: *Trichomonas vaginalis* 3.6 – 7.5; *Candida albicans* 5.4; *N. gonorrhoeae* 7.5; *B. proteus* 7.4; *Streptococci* 7.4; and Diphtheroids 7.2.<sup>3</sup>

Vaginal acidity is important for the maintenance of vaginal health and prevention of vaginal infections<sup>5</sup> as was suggested by O'Hanlon, et.al. When lactobacilli predominate the vaginal microbiota, women have significantly more lactic acid-mediated protection against infections like *N. gonorrhoeae*.<sup>5,6</sup>

An *in vitro* study conducted by Matu, et.al proved the inhibitory effect of *Lactobacilli* against pathogenic bacteria. The 158 lactobacilli cultures they used produced supernatants with a pH range between 2.62 and 6.71; the highly acidic (pH 2-3.99) supernatants being more inhibitory to the indicator strains. There was significant reduction in the mean zones of inhibition following chemical and physical treatment of the supernatants ( $p = 0.0025$ ).<sup>7</sup>

At present, there are pharmaceutical products that are designed to sanitize the vulvar and vaginal area without necessarily altering its physiologic pH. Paternoster et.al. reported that the use of an acidic gel in low-risk pregnant women is able to maintain a physiological vaginal ecosystem.<sup>8</sup> Although one study revealed no statistically significant variation in vulvar and vaginal pH using a lactic acid base feminine wash (pH 5.2) on 40 women,<sup>9</sup> Tanspusari et.al proved that among women over 18 years old without manifestations of vulvovaginal irritation or infection, a combination of lactoserum and lactic acid demonstrated high percentage of satisfaction and tolerability.<sup>10</sup>

Human safety tests on 9 feminine washes have been conducted in the Philippines by Chan in 2008. The study concluded that the products have low level of irritation potential, and safe for use among consumers with sensitive skin.<sup>11</sup>

Considering the possibility of altering the vaginal pH by a safe vaginal wash with different physiologic acidity, the content of feminine wash for everyday use has to be examined closely.

Available foreign studies used vaginal gels or tablets to determine if these products were able to maintain the vaginal pH within the physiological range. However, a computerized database search for local articles regarding use of feminine wash in maintaining the physiological vaginal pH among reproductive age and menopausal women yielded no result. This may be the first study conducted locally.

## OBJECTIVES

### General Objective

To determine whether FW-01, FW- 02, FW- 03, or FW-04 maintains normal vaginal pH and are acceptable among women of reproductive and menopausal age groups.

### Specific Objectives

1. To determine the mean difference vaginal pH via pH meter after using:
  - a. FW-01, FW-02 and FW-03 among women of reproductive age.
  - b. FW-02, FW-03 and FW-04 among menopausal women.
2. To compare the mean acceptability score of the following, using a validated suitability questionnaire:
  - a. FW-01, FW-02, and FW-03 among women of reproductive age.
  - b. FW-02, FW-03 and FW-04 among menopausal women.
3. To determine the proportion of women who will develop adverse effects in using FW-01, FW-02, FW-03 and FW-04.

### Definition of Terms

*Maintenance of vaginal pH.* pH monitoring values during the study trial within the physiologic range of 3.5 – 4.5 for adult women of reproductive age and 6.5 – 7.5 for menopausal women using a pH meter strip.

*Acceptability.* A mean score of 28 or higher based on the validated acceptability evaluation parameters.<sup>10</sup>

*Reproductive age group.* Women 18 to 42 years old.

*Menopausal age group.* Women whose last menstrual period occurred at least 12 months prior to enrolment in the study.

## MATERIALS AND METHODS

### Study Design

This is a randomized, double blind, three-period, three-way crossover clinical trial (Figure 1).

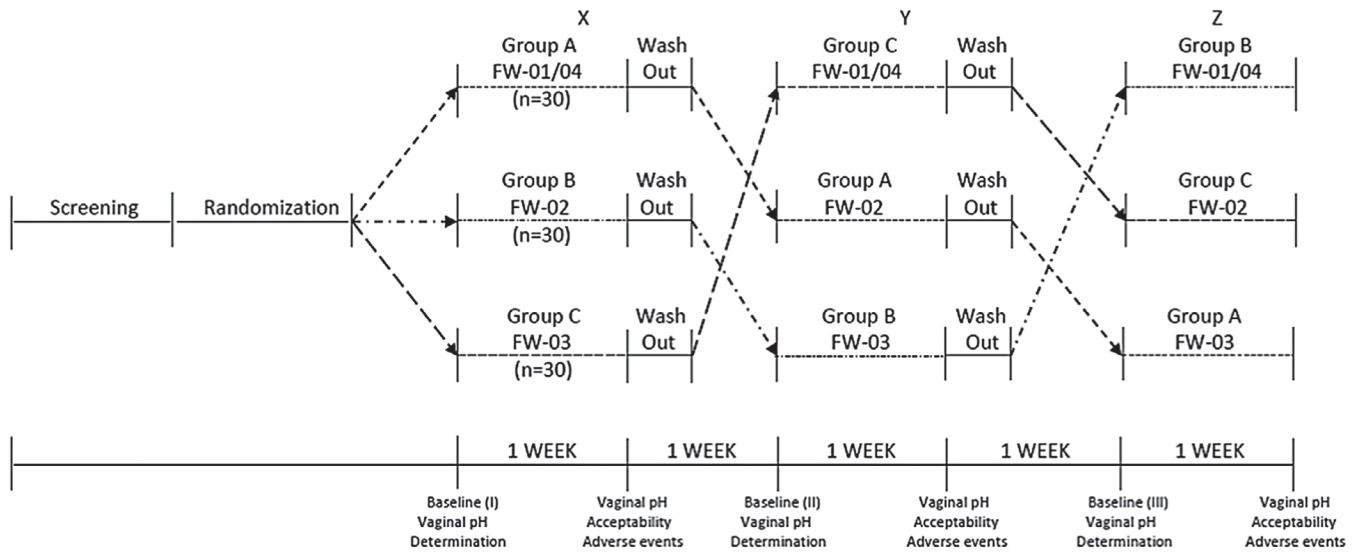
### Study Population

A total of 90 reproductive age women and 30 menopausal women consulting at the Out-Patient Department of FEU-NRMF Medical Center and the clinic of the principal investigator at the Marian Medical Arts Building in Fairview, Quezon City were enrolled.

### Sample Size

The estimate of the delta and standard deviation (SD) was based on the study of Bachmann, et al., involving seventy low-risk women pregnant with a singleton (second trimester) using acidic gel and placebo for 12-weeks. The mean vaginal pH after 12-weeks of treatment was  $4.3 \pm 0.3$  for both the acidic gel group and placebo group.

Since there was no variance in the vaginal pH between the two groups, a mean difference of 0.423 (reproductive age group) and 0.750 (menopausal age group) in vaginal pH were considered reasonable approximation to the expected difference between three treatments after 1 week.



**Figure 1.** Study design for feminine wash determination and acceptability study

The estimate of variability, to be conservative, was taken as the maximum SD from the 12-week study, which was 0.3. However, since the duration of the study was relatively short, the variability of the different treatments was higher. Therefore, an SD of 1 was estimated for this study.

Sample size was estimated for a 2-sided t-test at  $\alpha=0.05$  with 80% power, assuming delta is 0.423 and 0.75 for both groups and  $SD=1$ . Using a sample size calculator, the total sample size for this study was  $N=90$  (reproductive age group) and  $N=30$  (menopausal age group), respectively.

### Inclusion Criteria

Healthy females eligible in any of the following age groups:

1. Reproductive age (18 years old – 42 years old)
2. Menopausal age

### Exclusion Criteria

1. Women complaining of vaginal discharge/irritation.
2. Currently taking medications that may affect the vaginal pH, i.e. antibiotics and steroids for more than 7 days.
3. Women who had surgical menopause, i.e. those who underwent Total Abdominal Hysterectomy, Bilateral Salpingo-oophorectomy (TAHBSO)

### Sampling Frame and Technique

Census logbooks containing list of patients were used as sampling frame. From the list, convenience sampling was employed to screen study participants.

### Randomization

With three treatments per age group, there were 6 treatment sequences that could be created: 1-ABC, 2-ACB, 3-BAC, 4-BCA, 5-CAB, 6-CBA. To achieve greater balance

in the design, the 90 and 30 subjects in each age group were allocated to these treatment sequences using permuted-block randomization with fixed block sizes of 18 and equal numbers per treatment, i.e. there were 3 subjects each given 1 of the 6 treatment sequences per block. The STATA module RALLOC was used to generate the treatment allocations. Allocation concealment was done using central randomization by telephone (8:00 AM to 5:00 PM).

### Study Procedure

A total of 120 women ( $N=90$ , reproductive age group and  $N=30$ , menopausal age group) who have given informed consent satisfied all the inclusion criteria. For subjects who used any vaginal wash within one week prior to study inclusion, a one-week wash out period was done. Both age groups had three arms and had been studied in three periods. Subjects in each arm for both age groups were randomized to Group A, Group B or Group C. Prior to giving the study product, baseline characteristics including vaginal pH was determined. The vaginal pH was taken using a color-metered litmus paper (EMD Millipore® 1.09535.0001 MColorpHast® pH test strips)<sup>14,15</sup> measured in 0 to 14 pH range in a single test with 0.5pH sensitivity.<sup>16</sup> The strip was dabbed on the 5 o'clock position of the labia majora for the external pH and on the 5 o'clock position of the introitus for the internal pH. Each subject received one of the four feminine wash per study period. In the first period, Group A used FW-01, Group B used FW-02 and Group C used FW-03 for one week. After the first period, a repeat vaginal pH was determined. A minimum of seven (7) days washout period was done afterwards. After the first washout, baseline vaginal pH was determined prior to the start of the second period. The same steps were repeated for the subsequent visits using the treatment sequences assigned via permuted-block randomization. pH monitoring was

done by the principal investigator or the research assistant who were unaware of the treatment assignments.

In cases where the women would have their menstruation, the application of the investigational product (IP) was temporarily suspended and resumed the day after its cessation. The schedule of IP use and follow-up visits were determined by the remaining number of days corresponding to the prescribed IP use.

Sexual contact was only allowed during the washout periods; however, the participants were advised to abstain from any sexual activity 48 hours prior to their next visit. Likewise, should the subjects micturate prior to vaginal pH measurement, they were asked to wash with water prior to the procedure to avoid alteration of the pH levels.

## Outcome Measurements

### Primary Outcome

Maintenance of vaginal pH at physiologic pH – vaginal pH was measured using a pH meter and was assessed in terms of mean differences and standard deviations in vaginal pH post-feminine wash use from baseline.

Level of feminine wash acceptability – acceptability was measured using a validated questionnaire and was measured in terms of mean acceptability scores post-feminine wash use.

### Secondary Outcome

Safety profile of feminine wash - safety profile was assessed through reports of adverse reactions, if any, from using the different feminine wash. The outcomes were the number of adverse experiences and descriptive accounts of the subjects' experiences with product use.

## Data Analysis

Separate analyses were done for women of reproductive age and menopausal women. Mean and standard deviation of the vaginal pH were computed for each treatment group. Statistical significance of the differences in the treatment means of vaginal pH were assessed using 3-way analysis of variance (ANOVA) where the sources of variation were the treatment, order of administration and sequence. If treatment was found as a significant source of variation, Dunnett's multiple comparisons procedure was applied to determine if either FW-01 or FW-04 differed from FW-02 and FW-03. Significant differences in sequence means from the ANOVA results were examined to determine presence for possible carryover effects of treatments. The level of significance for all tests was set at 0.05. Intention to treat analysis was done.

Dropout from the study is defined as:

- Failure to use the investigational product for  $\geq 2$  days.
- Failure to visit at least once, specifically on visits 2, 4, and 6.

Withdrawal from the study is defined as:

- Any subject who has incurred a condition where using any of the investigational products are contraindicated.
- Any subject who opted to stop using any of the investigational products.

## RESULTS

### Analysis of women of reproductive age

#### Socio-demographic Characteristics

Of the 90 reproductive age women who participated in this study, the youngest was 17 years old while the oldest was 50. Majority belonged to the 30-39 age group with a mean of 32.8 years (SD=8.1). Most of the women were married (62.2%) and employed (54.4%).

One in 5 women had no history of sexual contact. Half of the population (52.6%) had history of hospitalization. There were 20 (22.2%) women who were taking medications, mostly pills. (Table 1)

#### pH Values

In all batches given FW-01, there was a decrease in the mean pH values. Over-all mean pH value change was -0.13 (SD=0.69). Batches given FW-02 had increased pH values. The mean change across all periods was 0.15 (SD = 0.82). Those given FW-03 had varying results. The overall mean change in pH value in FW-03 was 0.00 with SD = 0.75.

For FW-01, there was a trend to have a more acidic pH value (mean -0.13, SD 0.69) after treatment which was not seen in FW-02 and 03. However, this difference was not statistically significant.

However, using ANOVA (Table 2), there were significant differences in mean change in pH values among the three feminine wash products ( $F_{2,175}=3.30, p=0.0392$ ). The difference between FW-01 and 02 was found to be significant ( $p<0.05$ ). The pairwise comparisons with FW-03 were not significant for both FW-01 and 02. (Table 3) Period and sequence of treatment were not found to be significant sources of variation.

There was an over-all decrease in the mean pH values of -0.15 (SD=0.86) in FW-01. The mean change in the other two washes were much smaller. The mean change across all periods was -0.05 (SD=0.77). Over-all, the mean change in FW-03 was -0.04 (SD=0.82).

All products decreased the pH values toward a more acidic level (means= -0.15, -0.05, -0.04). However, this difference in treatment was not statistically significant.

There were no significant differences in the mean change in pH values among the feminine wash groups ( $F_{2,175}=0.49, p=0.6152$ ). Period and sequence were found to be non-significant sources of variation.

#### Acceptability

Majority of the subjects expressed 'extreme satisfaction' on the different features of the products except for the amount

of lather for FW-02 where less than half were 'extremely satisfied'. FW-03 consistently had the highest mean rating across all aspects of acceptability.

**Table 1.** Socio-demographic characteristics, lifestyle and medical history of the reproductive age women

| Age Group, n (%)                      | Frequency | Percent |
|---------------------------------------|-----------|---------|
| Less than 20                          | 10        | 11.1    |
| 20-29                                 | 21        | 23.3    |
| 30-39                                 | 35        | 38.9    |
| 40-50                                 | 24        | 26.7    |
| <b>Civil Status, n (%)</b>            |           |         |
| Married                               | 56        | 62.2    |
| Single                                | 34        | 37.8    |
| <b>Employment, n (%)</b>              |           |         |
| Employed                              | 49        | 54.4    |
| Not employed                          | 41        | 45.6    |
| <b>Sexual History, n (%)</b>          |           |         |
| With                                  | 72        | 80      |
| None                                  | 18        | 20      |
| <b>Hospitalization History, n (%)</b> |           |         |
| With                                  | 50        | 52.6    |
| Deliveries                            | 27        | 28.4    |
| Dilatation and curettage              | 7         | 7.4     |
| Dengue                                | 4         | 4.2     |
| Appendectomy                          | 3         | 3.2     |
| Pneumonia                             | 2         | 2.1     |
| Tubal ligation                        | 1         | 1       |
| Fracture                              | 1         | 1       |
| Malaria                               | 1         | 1       |
| Anemia                                | 1         | 1       |
| Cholecystectomy                       | 1         | 1       |
| Thoracostomy                          | 1         | 1       |
| Marsupialization                      | 1         | 1       |
| None                                  | 45        | 47.4    |
| <b>Medications, n (%)</b>             |           |         |
| With                                  | 20        | 22.2    |
| Pills                                 | 14        | 15.6    |
| Vitamins                              | 1         | 1.11    |
| Food supplement                       | 2         | 2.22    |
| Iron supplement                       | 1         | 1.11    |
| Salbutamol                            | 1         | 1.11    |
| Vildagliptin                          | 1         | 1.11    |
| None                                  | 70        | 77.8    |

**Table 2.** Analysis of variance for pH change in internal genitalia among reproductive age women

| Source                 | Sum of Squares | df  | Mean Square | F-ratio | p-value |
|------------------------|----------------|-----|-------------|---------|---------|
| Feminine Wash          | 3.55           | 2   | 1.77        | 3.30    | 0.0392  |
| Period                 | 0.68           | 2   | 0.34        | 0.63    | 0.5324  |
| Sequence               | 2.20           | 2   | 1.10        | 1.74    | 0.1816  |
| Subjects with Sequence | 54.93          | 87  | 0.63        | 1.17    | 0.1856  |
| Residual               | 94.05          | 175 | 0.54        |         |         |
| Total                  | 155.43         | 268 | 0.58        |         |         |

**Table 3.** Tukey's HSD test for pH change in internal genitalia among reproductive age women

| Group vs Group | Group means | Mean difference | HSD test          |
|----------------|-------------|-----------------|-------------------|
| 1 vs 2         | -0.13 0.15  | 0.28            | 3.64 <sup>†</sup> |
| 1 vs 3         | -0.13 0.00  | 0.13            | 1.74              |
| 2 vs 3         | 0.15 0.00   | 0.15            | 1.89              |

<sup>†</sup>significant at  $p < 0.05$ . Studentized range critical value (0.05,3,175) = 3.3430

The mean acceptability score was highest in FW-03 (32.48, SD=2.78). The differences in mean ratings were not statistically significant ( $p=0.0753$ ).

### Adverse Events

Itching was the only adverse event reported by the subjects.

### Analysis of women of menopausal age

#### Socio-demographic Characteristics

29 out of the 30 menopausal women completed the study. One patient expired due to myocardial infarction. The largest age group was 50 to 54 years old with an average of 56.3 years (SD=8.0). Majority were married and unemployed.

One in 3 of the women had no history of sexual contact. Twenty (20) of the women had previous hospitalizations and majority took anti-hypertensive medications. (Table 4)

#### pH Values

In FW-02, there was a decrease in the mean pH values in the first batch of subjects. Over-all mean pH value change in FW-02 was -0.04 (SD=0.43). In FW-03, there was a decrease in the mean pH value among the first and third batches while no change in mean pH value was seen in the second batch. The combined batches had a mean pH value decrease of -0.26 (SD=0.71). There were varying results for those who used FW-04 with a very small over-all change in mean pH value, +0.03 (SD=0.68).

Among all the products tested, only FW-04 changed the pH values toward the physiologic range for the menopausal age group (mean = 0.03, SD = 0.68). However, this difference was not statistically significant.

The differences in the mean change in pH values in the internal genitalia were not statistically significant among all products ( $F_{2,51}=1.40$ ,  $p=0.2568$ ). Period and sequence of treatment were not found to be significant sources of variation.

The mean pH value decreased in all batches given FW-02 (-0.36, SD=0.68). The mean change across all periods for

FW-03 was -0.11 (SD=0.80). Over-all, the mean increase in FW-04 was 0.17 (SD=0.71).

FW-02 significantly decreased the pH values toward a more acidic level (-0.36, p=0.0097) while FW-04 changed the pH values toward the physiologic range for menopausal women (0.17, p=0.2020).

**Table 4.** Socio-demographic characteristics, lifestyle and medical history of the menopausal age women

| Age Group, n (%)   | Frequency | Percent |
|--|-----------|---------|
| Less than 50   | 3         | 10.3    |
| 50-54  | 9         | 31.0    |
| 55-59  | 7         | 24.1    |
| 60-64  | 5         | 17.2    |
| 65 and above   | 5         | 17.2    |
| <b>Civil Status, n (%)</b>   |           |         |
| Married  | 22        | 75.9    |
| Single   | 6         | 20.7    |
| Widowed  | 1         | 3.4     |
| <b>Employment, n (%)</b>   |           |         |
| Employed   | 13        | 44.8    |
| Not employed   | 16        | 55.2    |
| <b>Sexual History, n (%)</b>   |           |         |
| With   | 20        | 69.0    |
| None   | 9         | 31.0    |
| <b>Hospitalization History, n (%)</b>  |           |         |
| With   | 18        | 62.1    |
| Deliveries   | 7         | 24.1    |
| Hypertension   | 4         | 13.8    |
| Others   | 7         | 24.1    |
| Kidney stones, cholecystectomy, laminectomy, thyroidectomy, mild stroke, cardiac disease, electrolyte imbalance, hypokalemia, excision of breast cysts |           |         |
| None   | 11        | 37.9    |
| <b>Medications, n (%)</b>  |           |         |
| With   | 15        | 51.7    |
| Amlodipine   | 5         | 17.2    |
| Losartan   | 4         | 13.8    |
| Simvastatin  | 2         | 6.9     |
| Salbutamol   | 2         | 6.9     |
| Metoprolol   | 2         | 6.9     |
| None   | 14        | 48.3    |

The differences in the mean change in pH values were found to be significant among the feminine wash groups ( $F_{2,51}=3.84$ ,  $p=0.0279$ ) using ANOVA. (Table 5) Tukey's HSD test showed that the mean change in pH value in FW-02 was significantly different from that of FW-04 ( $p<0.05$ ). Period and sequence were found to be non-significant sources of variation of the pH values. (Table 6)

**Acceptability**

Majority of the subjects were 'satisfied' or 'extremely satisfied' with all the products' features. (Table 5) FW-04 consistently had the highest mean ratings (31.96, SD=3.56) among the three products across all aspects of acceptability but the differences in scores were not statistically significant, ( $F_{2,37}=1.62$ ,  $p=0.2112$ ).

**Adverse Events**

No adverse events were reported by women of menopausal age.

**DISCUSSION**

**The vaginal ecosystem**

The vagina and its unique microbial flora form a well-balanced ecosystem, with the vaginal milieu controlling the bacterial types present and the microflora in turn controlling the vaginal ecosystem.<sup>12</sup> This ecosystem is dynamic and changes are influenced by age, contraception, frequency of coitus, number of sexual partners, sexual behaviors, as well as personal habits and practices.<sup>13,14</sup>

The interplay of several factors is important for the integrity of the vaginal ecosystem. This system is characteristically composed of a diverse array of bacteria, of which lactobacilli predominate. They play a significant role in maintaining a critical balance amongst population of the various organisms of the normal flora and regulate the growth of potentially pathogenic organisms, preventing disease. The mechanism of such regulation involves the production of lactic acid, hydrogen peroxide, bacteriocins and other microbicidal substances. Lactic acid produced by

**Table 5.** Analysis of variance for pH change in external genitalia among menopausal

| Source                 | Sum of Squares | Df | Mean Square | F-ratio | p-value |
|------------------------|----------------|----|-------------|---------|---------|
| Feminine Wash          | 4.60           | 2  | 2.30        | 3.84    | 0.0279  |
| Period                 | 0.11           | 2  | 0.06        | 0.09    | 0.9118  |
| Sequence               | 0.33           | 2  | 0.16        | 0.34    | 0.7138  |
| Subjects with Sequence | 12.46          | 26 | 0.48        | 0.80    | 0.7266  |
| Residual               | 30.52          | 51 | 0.60        |         |         |
| Total                  | 47.24          | 83 |             |         |         |

**Table 6.** Tukey's HSD test for pH change in external genitalia among menopausal women

| Group vs Group | Group means | Mean difference | HSD test |
|----------------|-------------|-----------------|----------|
| 2 vs 3         | -0.36 -0.11 | 0.25            | 1.68     |
| 2 vs 4         | -0.36 0.17  | 0.53            | 3.62†    |
| 3 vs 4         | -0.11 0.17  | 0.28            | 1.94     |

†significant at  $p<0.05$ . Studentized range critical value (0.05,3,51) = 3.4140

these organisms contribute to the state of acidity of the local environment or the vaginal pH. This is another important factor for maintaining a normal vaginal environment. Acidity results from the anaerobic metabolism of glycogen to lactic acid. The amount of glycogen in the vaginal epithelium, in turn, is dependent on estrogen activity.

### Range of pH amongst age groups

The range of pH in the vaginal area varies with age. The average vaginal pH values quoted in standard textbook is 6.0 – 8.0 in children, 3.5 – 4.5 in puberty/reproductive age group and pregnancy while it becomes alkaline at 7 during menopausal stage.<sup>2,3</sup>

Based on the studies by Bo et al,<sup>15,16</sup> the pH range of the external genitalia (labia majora and perineum) in the reproductive age group is 5.2 – 5.6, which falls within physiologic range of 4-6 of the skin in general.<sup>17</sup>

In a large epidemiologic study conducted in Costa Rica, vaginal pH was a functional index of aging and menopause. They reported that vaginal pH >5 have the sensitivity of 64-67% for the diagnosis of menopause.<sup>18</sup> A cut-off level of pH>4.5 have a sensitivity of 74-88%. In this study,<sup>19,20,21</sup> all the menopausal subjects have a pH >5 in the internal and external genitalia. Furthermore, evidence is presented to suggest that vaginal pH rises to >4.5 in 95% of women within 12 months of becoming hypoestrogenic.<sup>22</sup>

### Effects of feminine wash on vaginal pH: a comparison of three products

#### Reproductive Age Group

FW-01 when used as a daily perineal wash was associated with a decrease in the mean pH values of the internal genitalia more than that observed with FW-02 and FW-03. There were significant differences in mean change in pH values among the three feminine wash products ( $p=0.0392$ ). The difference between FW-01 and FW-02 was found to be significant ( $p<0.05$ ). Of the three, FW-01 appeared to be effective in maintaining a lower vaginal pH thus favoring a more acidic environment. However, for the external genitalia, there were no significant differences in the mean change in pH values among the feminine wash groups ( $p=0.6152$ ). All appear to be equally effective in maintaining the pH of the external genitalia within the physiologic range.

#### Menopausal Age Group

The results show no significant differences in mean change in pH values in the internal genitalia among the feminine wash ( $p=0.2568$ ). All have comparable effects on the vaginal mucosa. However, the differences in the mean change in pH values in the external genitalia were statistically significant ( $p=0.0279$ ). Pairwise comparison showed that the mean change in pH value in FW-02 was significantly different from that of FW-04 ( $p<0.05$ ), in favor of FW-04.

### User satisfaction: a comparison of three products

Majority of the subjects in the reproductive age group expressed 'extreme satisfaction' on the different features of the products. The differences in mean ratings among the feminine wash were not significant ( $p=0.0753$ ).

The mean acceptability score in the menopausal age group was highest in FW-04. However, the score differences were not statistically significant. The group reported no adverse reactions. There was a significant difference between FW-02 and FW-04 for the moisturizing effect, in favor of FW-04 ( $p=0.0137$ ).

### Feminine wash-facilitated restoration and maintenance of vaginal acidity: health implications

#### Vaginal Acidity and STIs

In response to estrogen, the vaginal epithelial cells of reproductive age women proliferate, their glycogen content is increased and subsequently, lactobacillus produces lactic acid from glycogen and causes an acidic pH, which maintains vaginal health. This acidity has been shown to be microbicidal for many sexually transmitted disease (STD).<sup>23,24</sup>

#### Vaginal Acidity and Menopausal Urogenital Conditions

Because of declining estrogen levels, menopausal women often present with symptoms of atrophic vaginitis or urogenital atrophy. Increased vaginal pH levels are associated with vaginal dryness and may predispose the vagina to infections. Using feminine wash may help maintain the pH within the physiologic range to prevent vaginal infections.<sup>13</sup>

#### Additional benefits

Moisturizers may be used in conjunction with estrogen replacement therapy or as alternative treatment.<sup>25</sup> Some patients may not choose hormonal replacement therapy because of its side effects. Moisturizers help maintain natural secretions and coital comfort hence using a moisturizing feminine wash may be preferred.

#### User satisfaction and patient compliance

Positive responses in patient satisfaction, the absence of adverse effects, and the additional satisfaction to the moisturizing effect in the menopausal group underscores that the use of feminine wash is a safe and viable health strategy to protect against various STIs. They can also address local urogenital conditions consequent to the decline of estrogen and rise of vaginal pH in older women.

Using feminine wash may help maintain the pH within the physiologic range thus prevents vaginal infection.

Good acceptability of use among the subjects implies good compliance and therefore, a practice that can be adopted on a long-term basis as part of a woman's good hygienic practice.

Most of the studies available are on internal genitalia pH levels. This is the first local study to include the pH of the external genitalia. Hence, studies should be conducted comparing the external and internal genitalia pH levels.

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### Statement of Authorship

All authors have approved the final version submitted.

### Author Disclosure

Two of the authors (JCB and GCM) are employed by ADP Pharma Corporation.

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### Note

Additional product information is available upon request from the authors.

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