

Effect of Ellage™ and Other PCCA Proprietary Bases on the pH of Vaginal Fluid

SUMMARY: The mildly acidic vaginal pH is the result of physiological processes and the microbiology flora. Ellage Anhydrous Vaginal, VersaBase® Cream and MucoLox™/VersaBase Gel (50:50) are unlikely to change the vaginal pH, which is essential for normal mucosal function and protection against infection.

Introduction:

The pH (potential of hydrogen) is a quantitative measure of the hydrogen ion concentration $[H^+]$ in a solution and it indicates if the solution is acid or alkaline. Mathematically, the pH corresponds to the negative of the base 10 logarithm of the H^+ molar concentration and is represented by the following formula: $pH = -\log_{10}[H^+]$.

The pH scale, also called the acid-base scale, ranges from 0 to 14 and it inversely indicates the $[H^+]$. As such, the higher the hydrogen ion concentration, the lower the pH. A solution with a pH less than 7 is considered acidic; a solution with a pH greater than 7 is considered alkaline, or basic; a solution with a pH of 7 is considered neutral, as displayed in Figure 1. The pH is commonly measured by a pH meter or, less accurately, by paper test strips [1].

The human body compartments and biological fluids have characteristic pH ranges that are very important to maintain a healthy balance of acidity and alkalinity. For instance, the normal physiological pH of the blood is 7.3-7.5 whereas the pH of the vagina is moderately acidic ≈ 4.5 . Any disruptions of these acid-base balances can lead to the development of a variety of diseases [2]. The purpose of this *in vitro* study is to investigate the effect of the PCCA proprietary bases Ellage Anhydrous Vaginal, VersaBase Cream and MucoLox/VersaBase Gel (50:50) on the pH of vaginal fluid, in comparison to an over-the-counter (OTC) long-lasting vaginal moisturizer.

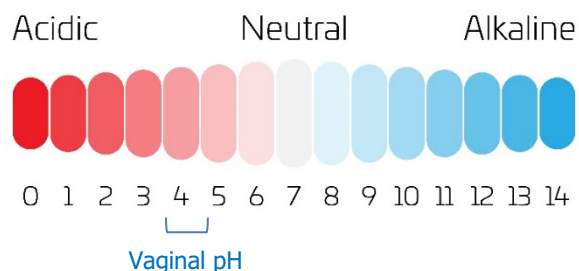


Figure 1. The pH scale, adapted to indicate vaginal pH; stock illustration ID: 1215457015 (adapted from Pty /Shutterstock.com).

Methodology:

A Vaginal Fluid Simulant (VFS) was prepared in the PCCA R&D Lab to model the fluid produced in the human vagina by healthy, nonpregnant premenopausal women. The composition of the fluid medium, displayed in Table 1, was based on the research by Owen and Katz (1999) who gave particular importance to the pH and osmolarity of the VFS [3].

About 50 mL of the VFS were placed in a water bath until 37°C. The pH of the VFS was measured using a HORIBA compact pH meter (LAQUAtwin-pH-22) and an average of 4 readings was considered baseline. A small volume of 0.5 mL of VFS was removed and added to a beaker. A total of 5 g of Ellage Anhydrous Vaginal was added to the beaker and mixed gently. The pH of the resulting solution was measured in duplicate. Again 0.5 mL of VFS was removed and added to the same beaker, followed by another set of pH measurements. This procedure was repeated for the following volumes of VFS: 4x1 mL and 2x2.5 mL, up to a total of 10 mL of VFS. This *in vitro* study was repeated for 5 g of VersaBase Cream, 5 g of MucoLox/VersaBase Gel (50:50) and 5 g of the OTC vaginal moisturizer.

Ingredient	Quantity
NaCl	3.51 g
KOH	1.4 g
Ca(OH) ₂	0.222 g
BSA	0.018 g
Lactic acid	2.0 g
Acetic acid	1.0 g
Glycerol	0.16 g
Urea	0.4 g
Glucose monohydrate	5.0 g
HCl	qs pH 4.2-4.5
H ₂ O	qs 1,000 mL

Table 1. Composition of the Vaginal Fluid Simulant prepared in the PCCA R&D Lab.

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Results and Discussion:

The pH ranges obtained in this study for the VFS and the PCCA proprietary bases were as follows: Ellage Anhydrous Vaginal [pH 4.51-4.645]; VersaBase Cream [4.535-4.935]; and MucoLox/VersaBase Gel (50:50) [4.465-4.68] (Figures 2-4).

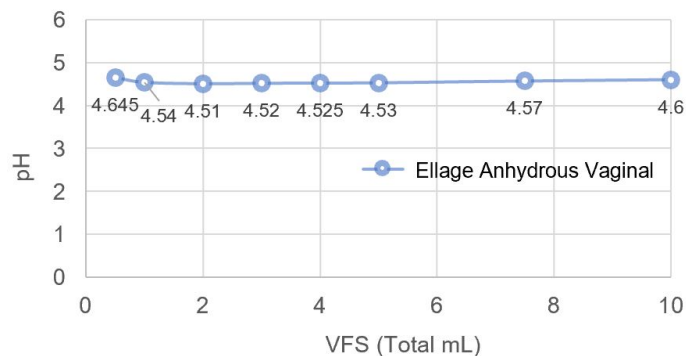


Figure 2. Effect of Ellage Anhydrous Vaginal (5 g) on increasing volumes of VFS (0.5 – 10 mL).

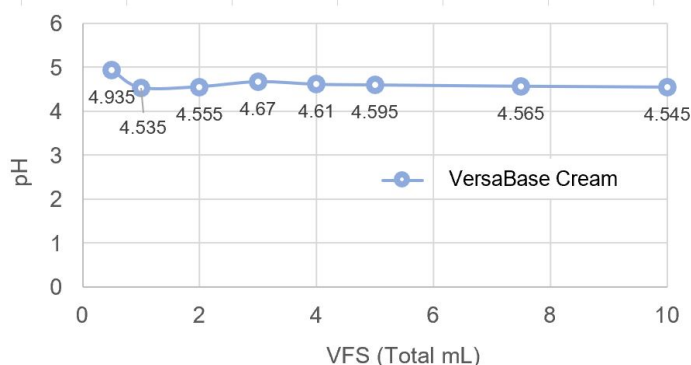


Figure 3. Effect of VersaBase Cream (5 g) on increasing volumes of VFS.

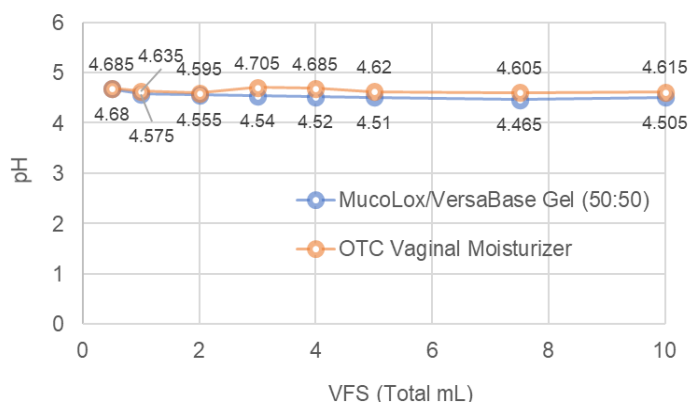


Figure 4. Effect of MucoLox/VersaBase Gel (50:50) and the OTC vaginal moisturizer (5 g) on increasing volumes of VFS.

Considering that the baseline pH of the VFS was 4.54, the PCCA proprietary bases had no significant effects on the pH of the fluid medium. In comparison, the OTC long-lasting vaginal moisturizer had also no significant effects on the VFS pH (Figures 2-4).

Conclusions:

The pH of the vagina is the result of physiological processes and the microbiology flora. It is important that the vaginal pH is kept mildly acidic ≈ 4.5 for normal mucosal function and protection against infection [2].

Any significant changes of vaginal pH are of clinical importance. For instance, a change to an elevated vaginal pH indicates an alteration of the microbial ecosystem which may result in bacterial vaginosis. In pregnant women, this elevated pH may indicate risk factors for preterm birth [2].

For these reasons, it is essential that feminine hygiene products and topical medications do not alter the vaginal pH when applied to the vaginal mucosa. This *in vitro* study has demonstrated that the PCCA proprietary bases Ellage Anhydrous Vaginal, VersaBase Cream and MucoLox/VersaBase Gel (50:50) are unlikely to contribute to any changes of the vaginal pH. This finding is key for compounding pharmacists to ensure the quality and safety of their vaginal formulations.

References:

1. The Editors of Encyclopaedia Britannica (2020) PH, Chemistry. *Encyclopaedia Britannica, inc.* (Accessed: August, 30).
2. Linhares, I.M., Summers, P.R., Larsen, B., Giraldo, P.C., Witkin, S.S. (2011) 'Contemporary perspectives on vaginal pH and lactobacilli'. *American Journal of Obstetrics & Gynecology*, 204 (2), p. 120.e1-5. doi: 10.1016/j.ajog.2010.07.010.
3. Owen, D.H., Katz, D.F. (1999) 'A vaginal fluid simulant'. *Contraception*, 59 (2), p. 91-5. doi:10.1016/s0010-7824(99)00010-4.