



## Research Article

# Study of the Cutaneous Tolerability and Safety of V-Bath-an Intimate Hygiene Daily-use Product

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### Abstract

**Background/Objective:** Several products containing various combinations of lactic acid, aloe vera, milk protein or lactoserum are commercially available, however evidence of its effectiveness in maintaining physiological pH and other subjective parameters in Indian women is lacking. Hence, to confirm the compatibility and tolerability of the intimate hygiene product V-Bath which is a combination of lactic acid, aloe vera, and milk protein when used daily, the current study was undertaken.

**Method:** This was a prospective, open-label, cross-over and single-center study in healthy female volunteers conducted under the supervision of dermatologists.

The test product was V-Bath Intimate Wash and the control products were two bathing soaps to be used by an equal number of females for 7 days prior to or after crossover depending on their usage of products before participation in the study.

At baseline or day 0, week 1 and week 2, each subject underwent clinical assessment for cutaneous tolerability and safety; at the same time points, subjects' assessment was obtained using a sensory questionnaire with scores for each parameter.

pH assessments were done at the same time points (Day 0, week 1 and week 2) by measuring pH before and after usage of the V-Bath and soap at the centre.

**Statistical analysis used:** A paired 'T' test with a 2-sided significance level of 5%.

**Results:** None of the thirty-three subjects reported erythema, itching, boils, foul smell, burning sensation, swelling, watery discharge or white/yellow discharge during the study period in response to the intervention of V-Bath or comparator soaps. There was no significant skin intolerance experienced by any of the subjects after the use of V-Bath for 7 days.

According to the analyses of the subject self-assessment records, a significant proportion of the population agreed that the product (V-Bath) was able to prevent odor, irritation and itchiness and provided moisturization and a soothing effect on the skin with single-use as well as regular 1-week use. The decrease in pH of the intimate area remaining from baseline (pre-wash) to the post-1-week use was significant ( $p=0.0230$ ) with V-Bath unlike soap which was not found to be significant.

**Conclusion:** V-Bath is a well-tolerated product suited for maintaining daily intimate hygiene in females.

### Keywords

Intimate hygiene; Aloe-vera; Lactic acid; Physiological pH; V-Bath

### Introduction

Maintaining hygiene is important for the general well-being of a person; intimate hygiene is a part of general hygiene. Nevertheless, the products used for the latter should be specifically formulated, since the skin in this area is different from the rest of the body in terms of moisture levels, pH and microbial flora [1].

Lactic acid is normally produced by the lactobacilli present in the vagina, which, along with keratinized epithelium generally prevents bacterial, trichomonal and fungal infections. However, in otherwise healthy females' menstruation, hormonal factors, excess body weight, weather conditions or clothing style may affect the acidic environment and increase the risk of infection [2]. Also, excessive dryness of the skin triggers itching which may also raise the chances of infection [3].

Further, improper hygiene practices also tend to disturb the pH and consequently the flora in the perineal region. Overzealous cleaning and use of soaps with alkaline pH, alcohol-based cleansers, hot water tend to dry the skin and increase the pH of the vulvar area leading to irritation of the skin and dermatitis ending in infections, if untreated [2]. Hence, it is important to use feminine wash products formulated and tested specifically for the vulvar area to ensure that they do not cause skin irritation or sensitization [4].

Therefore, a prospective study in healthy adult females, half of whom perceived to have sensitive skin was undertaken. V-Bath, an intimate hygiene product that contains milk protein, lactic acid and Aloe vera was tested for its overall effect on vulvar skin and its pH.

Natural ingredients used for intimate hygiene have demonstrated a positive clinical effect favoring the reduction of pH, the improvement of symptoms and the quality of sexual activity in all age/conditions observed [5,6]. Among the Genus Aloe, Aloe vera (*Aloe barbadensis* Miller) has been the most popular in both folk and -official medicine. Daily use of Aloe vera containing products has been reported to have a humectant effect on the skin, which was usually immediate. Thus, it is a proven effective ingredient for improving skin hydration without any occlusive effect (no effect on TEWL) [7]. Possibly, it would soothe or soften the skin when used in an intimate wash since it contains mucopolysaccharides, which help in binding moisture into the skin [8].

Lactic acid may aid local acidification which may restore the acidic pH and consequently the physiological microbial flora [2]. Hence, supplementation of lactic acid with Aloe vera and milk protein may help in maintaining an acidic pH and a skin-softening effect. To confirm these effects with the regular use of V-Bath and determine its tolerability, a prospective study in healthy adult females was conducted.

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## Objective

The objective of this prospective, open-label, cross-over study in healthy female volunteers was to confirm the compatibility and tolerability of the intimate hygiene product V-Bath and to study its effect on the pH of the vulvar area for 7 days.

## Patients and Methods

### Study design

This was a prospective, open-label, cross-over single-center study in healthy female volunteers conducted under the supervision of dermatologists. The study was conducted by MS Clinical Research Private Limited, Clinical Research Organization (CRO), Bengaluru. The study design, data management and statistical analysis were also performed by the same CRO. A written study-specific Informed Consent form was signed by the subjects willing to participate in the study as per the ICH-GCP code of ethics. This study was sponsored by Lupin Limited, India.

The study included thirty-three healthy, adult Indian females, as determined from their recent medical history. The age of the participants lied between 18 and 45 years. It was a mixed population of consumers and non-consumers of intimate wash in approximately an equal ratio. Females (50%) who perceived to have sensitive skin in the vulvar area as per their responses to the pre-study questionnaire were also a part of the study. The enrolled patients were to refrain from using any other intimate wash product(s) during the course of the study.

Females with a known history of allergic response to any cosmetic products, acute vaginal infection, undergoing treatment with oral medications (e.g. steroids, anti-oxidant), suffering from chronic illness which may influence the cutaneous state, any underlying uncontrolled medical illness including diabetes mellitus, hypertension, liver disease or history of alcoholism, HIV, hepatitis, or any other serious medical illness were excluded from the study.

### Intervention and assessments

The test product was V-Bath Intimate Wash containing Aloe vera, lactic acid, and milk protein. A coin size was to be used once daily during bath over external genitals or vulva. Subjects who were intimate wash consumers were given V-Bath in the first week before cross over and remaining subjects who were non-consumers of intimate wash were given either Dove or Dettol soap. The soap products were used by a nearly equal number of females prior to or after crossover in

order to create an average response and avoid product bias with the chosen soap. Since this study is a simple cross over design, soap is just a comparator and not a negative nor a positive control. The soap was to be lathered as required and used similar to V-Bath viz., once daily during bath.

At baseline or day 0, week 1 and week 2, each subject underwent clinical assessment for cutaneous tolerability and safety; at the same time points, subjects' assessment was obtained using a sensory questionnaire with scores for each parameter. The dermatological assessment included determination of the presence of either erythema, dryness, itching, boils, foul smell, burning, swelling, watery discharge or yellow/white discharge.

The subjects' self-assessment was based on positive or negative feedback regarding the prevention of odor, irritation and itchiness after the use of V-Bath. Questions about the feeling of cleanliness, moisturization and soothing effect with the use of V-Bath were also included in the forms.

pH assessments were done at the same time points (Day 0, week 1 and week 2) by measuring the pH of the vulvar skin before and after usage of the V-Bath and soap at the centre. The female subjects were provided with appropriate instructions to use and submit the litmus paper for evaluation.

## Results

All the thirty-four female subjects screened, fulfilled the inclusion criteria and were therefore enrolled in the study. One subject was lost to follow-up. Analyses were performed using descriptive statistical methods. A paired 'T' test with a 2-sided significance level of 5% (p-value<0.05) was used to determine significance levels on continuous variables such as pH.

Dermatological and subject self-assessments for skin compatibility and tolerability are tabulated in terms of frequency against its reaction and severity.

Among the thirty-four females who underwent a dermatological evaluation, mild dryness was noted only in one at baseline. None of the other subjects reported erythema, itching, boils, foul smell, burning sensation, swelling, watery discharge or white/yellow discharge during the study period. No significant irritation reaction was noted in any of the subjects. There was no significant skin intolerance experienced by any of the subjects after the use of V-Bath for 7 days.

According to the analyses of the subject self-assessment records, a significant proportion of the population agreed (recorded as 'Yes')

Table 1: Subject Self-assessment based on sensory questionnaire.

S. No.	Subject self-assessment Questionnaire parameters after use of V-Bath	After single-use (Day 0-Ti)			After 1-week use		
		N=17			N=33		
		Subject (%)		P value (Yes vs. No)	Subject (%)		P value (Yes vs. No)
'Yes'	'No'	'Yes'	'No'				
1	Prevents odour	100	0	<0.0001	100	0	<0.0001
2	Provide a fresh (clean) feeling	94.12	5.88	0.0003	100	0	<0.0001
3	Whether fresh (clean) feeling lasted through the day	64.71	35.29	0.3323	93.94	6.06	<0.0001
4	Prevents or reduces irritation	92.35	17.65	0.0127	100	0	<0.0001
5	Prevents or reduces itchiness	92.35	17.65	0.0127	100	0	<0.0001
6	Gently cleansing of intimate skin	100	0	<0.0001	100	0	<0.0001
7	Provides soothing effect on the skin	58.82	41.18	0.6291	100	0	<0.0001
8	Helps reduce dryness	100	0	<0.0001	87.88	12.12	<0.0001

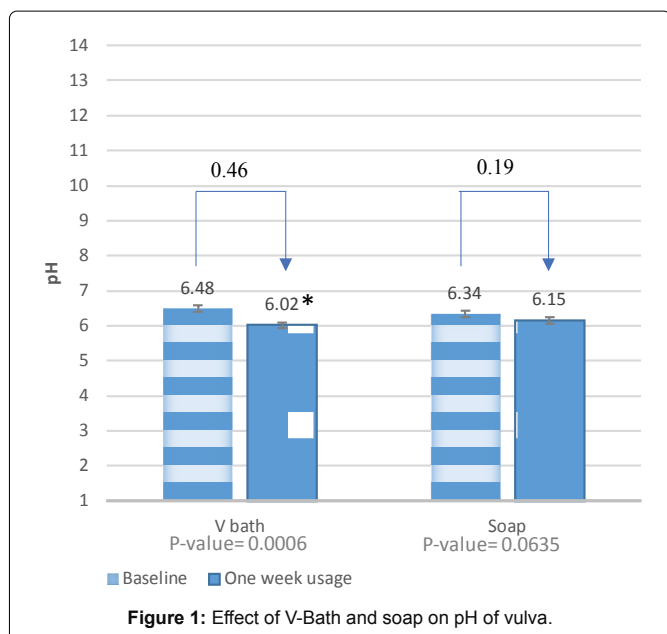


Figure 1: Effect of V-Bath and soap on pH of vulva.

that the product (V-Bath) was able to prevent odor, irritation and itchiness. Moreover, a significant proportion also affirmed that V-Bath helps reduce dryness, irritation and itchiness, provides a clean feeling, prevents odor at both time points with single-use as well as regular 1-week use (Table 1).

The decrease in pH of the vulvar area from baseline (pre-wash) to the post-1-week use was significant (p-value=0.0006) with V-Bath; whereas the decrease in pH with soap was not found to be significant (p-value=0.0635, at CI-95% not significant). The pH was noted to be in the physiological range for the vulvar area (Figure 1).

The pH dropped significantly by 0.46 when subjects used V-Bath for one week compared to 0.19 when they used soap for the same duration.

## Discussion

In females, physiological microbial flora of the vulva and acidic vaginal pH are important defense mechanisms to protect against microbial invasion [4]. Among other factors, such as immune deficiency, hormonal changes, stress; use of a vaginal douche or soap to clean the vagina, may disturb the normal flora resulting in irritation and infections.

Therefore, products used for maintaining intimate hygiene in females should be appropriately formulated. Further, these products should be tested precisely for the vulvar area to confirm that they do not cause skin irritation or sensitization [4].

Along with hypoallergenicity, soap-free, mild cleanser, absence of irritants, offering protection against dryness, maintenance of balanced microflora which is important characteristics, being pH friendly is one of the critical features of an intimate hygiene product [4].

The RCOG guidance on vulvar care recommends against the use of soap, shower gel, scrubs, bubble bath, deodorant, baby wipes, or douches on the vulva. It also suggests cleaning the vulva only once a day [4].

When evaluating previously published evidence, two studies

were retrieved which evaluated the effect of intimate wash on various parameters. Bahamondes et al., studied the efficacy of an intimate wash containing lactic acid and lactoserum for the prevention of Bacterial Vaginosis (BV) recurrence in Brazilian women after treatment and cure with oral antimicrobials [9]. Another intimate care solution containing burdock (*Arctium majus*), chamomile (*Chamomilla recutita*), and aloe (*Aloe barbadensis*) was evaluated as an adjuvant in Spanish women with vulvovaginitis of suspected infectious etiology. It demonstrated an effective reduction of the manifestations of the infection namely pruritus, erythema, edema, and vaginal discharge. The pH (5.47) remained unchanged [10].

It was observed that though there were several intimate care products commercially available, evidence on its effectiveness in maintaining daily intimate hygiene in Indian women was lacking. Particularly, the effect of a combination of lactic acid, Aloe vera and milk protein-containing intimate wash on pH has not been studied, though data on lactic acid and lactoserum is published for prevention of recurrence of BV. Also, it is noteworthy that evidence has established that vaginal pH varies with ethnicity.

Considering the above factors and available guidance, a prospective study was deemed appropriate to prove that the product V-Bath is dermatologically well tolerated and maintains physiological pH. Hence, this study was undertaken.

In this perspective, open-label and single-centre study in thirty-three healthy female subjects, dermatological and subject self-assessments noted that the Aloe vera and lactic acid-containing product V-Bath was not only well-tolerated but also prevented odor, irritation and provided a feeling of freshness all day long. After one week of regular use, V-Bath was noted to maintain the pH in the physiological range (5.5 to 6.5) of the vulvar area.

## Conclusion

The Study on pH and Hygiene (SOPHY) evidenced that appropriate intimate hygiene can be an important tool in women's everyday life. Hence, the use of V-Bath as a regular intimate hygiene wash provides a valuable alternative to soaps that alter the pH, cause discomfort and in some cases increase the risk of infections. Through this study, it is confirmed that V-Bath is well-tolerated and a useful product suited for maintaining daily intimate hygiene. V-Bath is thus dermatologically approved and well-tolerated by females with normal to sensitive skin type with no significant skin irritation.

## Acknowledgement

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## Conflict of Interest

The authors declare that there is no conflict of interest.

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