

## Egyptian Dermatology Online Journal Volume 9 Number 2

### **Evaluation of Antimicrobial, Safety and Efficacy of Medimix bathing bar with Sandal and Eladi oil**

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**Egyptian Dermatology Online Journal 9 (1): 3, December 2013**

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**Submitted:** 11 July 2013

**Accepted:** 15 October 2013

#### **Abstract**

Hygienic conditions are necessary for maintaining good health in homes, communities, businesses (especially those that are food related) and in health care settings. Nosocomial infections and person to person transmission of pathogenic organisms has become a problem that is costing healthcare facilities and patients millions of dollars every year. This study was a prospective, a single center, open label study to evaluate the antimicrobial, safety and efficacy of Medimix bathing bar with Sandal and Eladi oil conducted on 35 volunteers. The investigational product was presented as a coded bathing bar with pleasant odor. The parameters like the skin compatibility, complexion improvement, moisturizing effect, reduction in dryness of skin, reduction in oiliness of the facial skin, black/ white head clearance, soothing and smoothening effect, hyper/hypo pigmentation, acne, body odor, cleansing effect, itches and cracks were monitored and graded as per ethical guidelines of Declaration of Helsinki, during May 2007. Final observations of the study of bathing bar include very good skin compatibility, improvement in complexion, soothing and smoothening effect with good moisturizing effect and very good reduction in black/white heads, hyper/hypo pigmentation, acne, body odor, itching and cracks. The bathing bar was showing minimum inhibitory concentration at 1.25 mg/ml against *Staphylococcus aureus*, *Micrococcus* sp., *Malassezia furfur* and *Candida albicans* and 2.5 mg/ml against *Staphylococcus epidermidis* and *Corynebacterium diphtheriae*

## Introduction

Medimix bathing bar with Sandal and Eladi oil was formulated with special herbal ingredients to treat some of the common disorders listed below;

Acne vulgaris is one of the most common skin disorders in youth especially during the puberty. It is a chronic inflammatory disorder of pilosebaceous follicles that affects more than 85 percent of adolescents and young adults. Body odor is caused by apocrine, eccrine and sebaceous glands which generate fluids and chemical substances. Although sweating plays an important role, the classic association of sweat and body odor is only part of the explanation. It is true that unwanted body odor, occurring mainly in the axilla and the feet, is only indirectly caused by the secreted sweat but It is actually caused by bacteria living on the skin which find ideal conditions for growth in the warm areas of the body that tend to stay moist. They metabolize certain compounds found in sweat, leading to the occurrence of unwanted body odor [1].

The three most frequently used methods to combat body odor are to mask the smell with perfume, to reduce the quantity of sweat and to inhibit the odor producing bacteria. The microorganisms present in the underarm area include gram positive bacteria of the Corynebacterium, Staphylococcus, Propionibacterium and Micrococcus. The biological degradation of certain steroids by Coryneform bacteria is mainly responsible for the development of odiferous compounds. [1]

Loss of color or hypopigmentation is common to all races and occurs in disorders such as the poorly understood vitiligo. This effect, unsightly in white skins, can be devastating in black skins. Darkening of the skin or hyperpigmentation, again occurring in all races, can be a particular problem for black women as a result of hormonal changes during pregnancy, or the use of the contraceptive pills. Both darkening and lightening of the skin can occur as the horny layer of the skin heals after the damage caused, for example, by spots and rashes. Sometimes there is a chance of hyper pigmentation caused by Malassezian infection. These organisms may produce a compound called azelaic acid resulting in pityriasis versicolor. Poor Complexion, even though is not a skin problem, where the color of the skin is due to the existence of pigment bodies known as melanin. Melanin is produced by melanocytes present in the basal layer. The color of the skin is determined by the amount and type of melanin produced.

The purpose of moisturizing products is to restore and maintain the skin in a good looking, fully moisturized condition. To maintain this condition, the stratum corneum must be in a fully hydrated condition that allows flexibility and elasticity. Because of the observed medicated soaps and antimicrobial effects it is recommended that irrational and long term usage of these products should be discouraged. It is also important that during development of topical antimicrobial products, a multidimensional approach be adopted. This will ensure that the resultant product is designed for the specific needs of the market and that those needs are met. Ultimately the product is more likely to have a long, useful and profitable utilization. [2]

Medimix bathing bar with Sandal and Eladi oil contains 46 special herbal ingredients which are taken from classical Ayurvedic text books and include benefits of antimicrobial and antidermatophytic effects, preventing excess sebum production, itching and body odor,

brightness of the skin complexion, coolant to the skin, antioxidant, anti-inflammatory, antiaging, antiseptic effects etc. [3]

## Study aim

This study was planned to evaluate the antimicrobial activity, safety and efficacy of Medimix bathing bar with Sandal and Eladi oil.

## Materials and Methods

### Study Design

This study was a prospective, a single center, open label study to evaluate the safety, efficacy of the soap bar conducted on 35 volunteers, at the department of Dermatology of The Apollo hospitals, Chennai, India, as per the ethical guidelines of Declaration of Helsinki, during May 2007. The study protocol, case report forms, regulatory clearance documents, product related information and informed consent form were submitted to the "Institutional Ethics committee" and were approved.

### Safety and Efficacy studies

#### *Inclusion criteria*

A total of 35 consented volunteers were screened by the Principal investigator as per the protocol criteria like, males or females above 18 years of age, able to consent and volunteered for this study.

	<b>Age wise Distribution</b>		
No	Range	Male	Female
1	19 - 23	5	13
2	24-28	5	7
3	29-35	5	0

No	<b>Skin type</b>		
		Male	Female
1	Dry Skin	0	2
2	Oily Skin	11	15
3	Rough Skin	4	3

<b>Skin Complexion distribution</b>		
Types	Male	Female
Type II	3	3
Type III	6	14
Type IV	5	2
Type V	1	1

<b>Place of Work</b>		
Work Place	Male	Female
Non – Air conditioned area	8	6
Air conditioned room	7	14

Frequency	<b>Dietary Habits</b>					
	Coffee/day	Chocolates	Nuts/day	Bev/day	Milk/day	Protein drink
1 - 2	5	24	29	29	29	27
2 - 4	17	11	6	6	5	6
4 - 6	13	0	0	0	1	0

### ***Exclusion criteria***

Volunteers with boils/ acne in the body, skin irritation, skin allergy and rashes, hypersensitivity to normal vegetable oil (Coconut oil) and who were under medical treatment for skin infection were excluded from the study.

### ***Study Procedure***

A baseline history was obtained in order to determine the patient's eligibility for enrolment in the trial. The baseline assessment included personal data, a description of symptoms and details of past medical history like rough/oily/dry skin, acne, pigmentation, photosensitivity, itching/irritation, boils/scars, use of any medication and infection, blemishes, eczema, body odor, worm infestation, allergy, itching, constipation, stress/mental fatigue (condition characterized by excessive mental tiredness), hepatitis/viral Infection, cracks, dandruff and any other complaint.

### ***Follow up and Monitoring***

All the volunteers were provided with Medimix soap with Sandal and Eladi oil required for a period of 1 month and were under examination a weekly follow up visits, to check the improvement in all the respective parameters. Any volunteer who develops any adverse reactions or clinically significant abnormal laboratory tests values was evaluated by the Principle investigator and will be treated and / or followed up until the symptoms or values return to normal or acceptable levels as judged by the investigators. All adverse experiences will be documented in the case report form as well as in the volunteer's case file.

Evaluation parameters include: skin compatibility, improvement in complexion, moisturizing effect, reduction in dryness of skin, reduction in oiliness of skin, reduction in black/white heads, soothing & smoothing effect, hyper/ hypo pigmentation reduction, acne reduction, body odor, cleansing effect, itches and cracks. The completed case reports were collected and checked for completion, clarity and accuracy. The verified data were collected, compiled and analyzed. During the study period the adverse reactions in volunteers were recorded for irritation, burning sensation, allergy, rashes, itching and erythema / discoloration

### **Antimicrobial activity**

#### ***Test organism***

Staphylococcus epidermidis (MTCC 435), Malassezia furfur (MTCC 1374), Corynebacterium diphtheriae, Micrococcus species, Staphylococcus aureus (MTCC 1144) and Candida albicans of clinical origin procured from CAS Botany were used for the study. The cultures were sub-cultured and maintained on nutrient agar slants for bacterial cultures and Sabourauds dextrose agar slants for fungi and stored in refrigerator at 4oC. [4]

#### ***Inoculum preparation***

Inoculum of Staphylococcus epidermidis, Micrococcus species, Staphylococcus aureus, Corynebacterium diphtheriae, Malassezia furfur, and Candida albicans were prepared by inoculating in 10 ml of respective broth and incubated at 37oC for 24 hrs for bacteria and 30oC for 24 hrs for fungi. The inoculum size was adjusted to 10<sup>8</sup> cfu/ml using Mc Farland standard. [4]

#### ***Minimum Inhibitory Concentration (MIC) Test***

Stock solution of 10 % Medimix ayurvedic soap with Sandal and Eladi oil was prepared. From this stock doubling dilution of soap solution were done, transferred and labeled in sterile Petri plates and mixed with sterile molten Mueller Hinton agar for bacterial culture and Sabouraud dextrose agar (with olive oil for Malassezia furfur and without olive oil for Candida albicans) for fungal culture. After solidification the plates were inoculated with 10<sup>8</sup> cfu/ml of respective culture with culture control. The absence of growth at lowest concentration was noted as minimum inhibitory concentration (MIC in mg/ml). [4]

## Results

A total of 35 volunteers included in this study were in the age range of 18-35 years. The results are given in the Figure (1-13).

Skin compatibility was rated as good from II visit by 30 volunteers. From the third week 28 volunteers' perceived very good skin compatibility and 30 volunteers were rated as very good from 4th week. 4 volunteers' had rated as excellent from 4th week. (Fig.1)

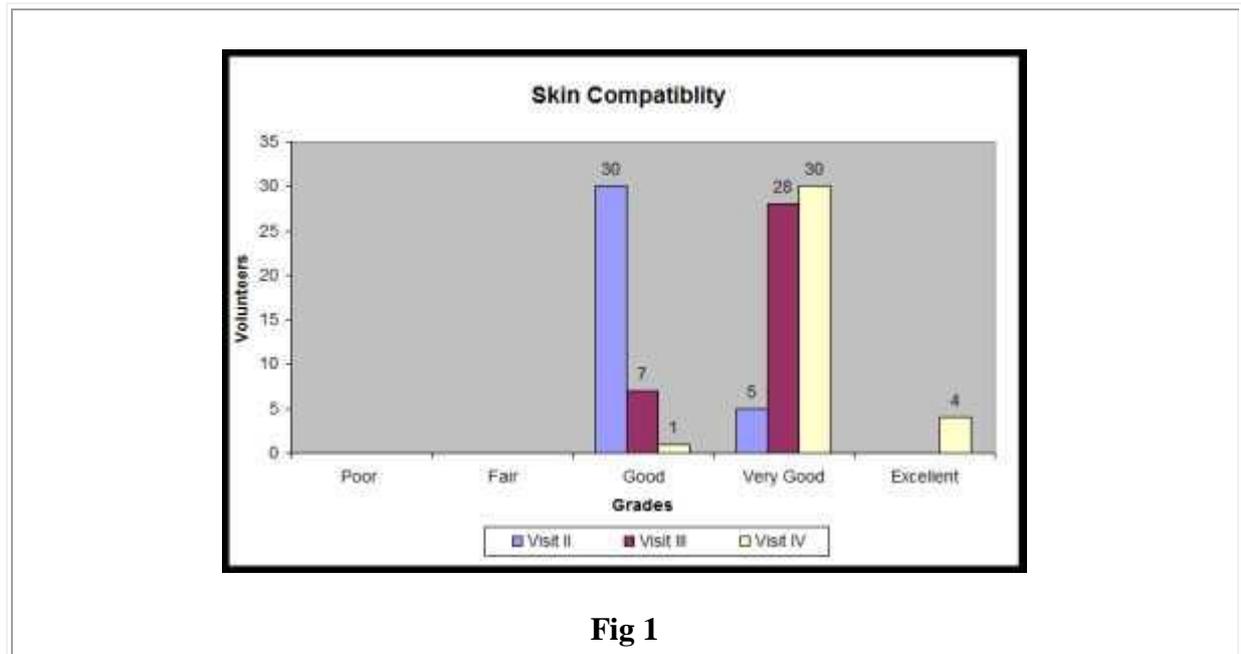
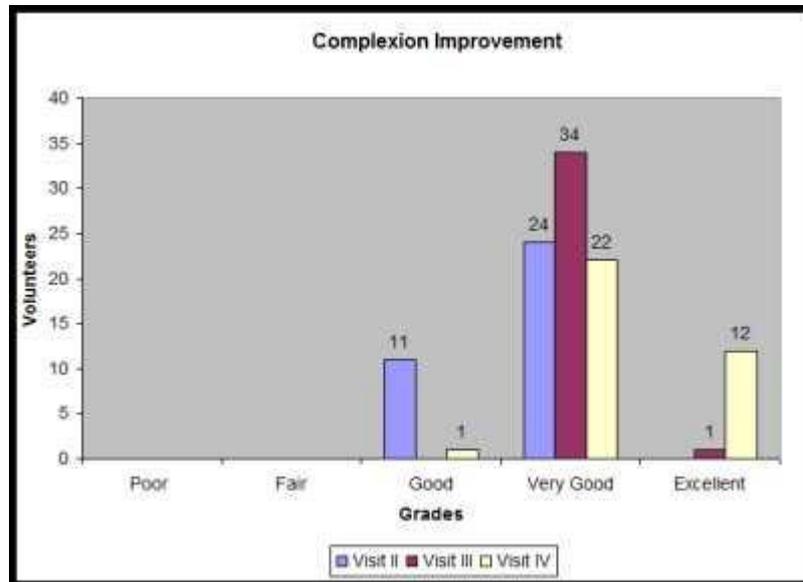


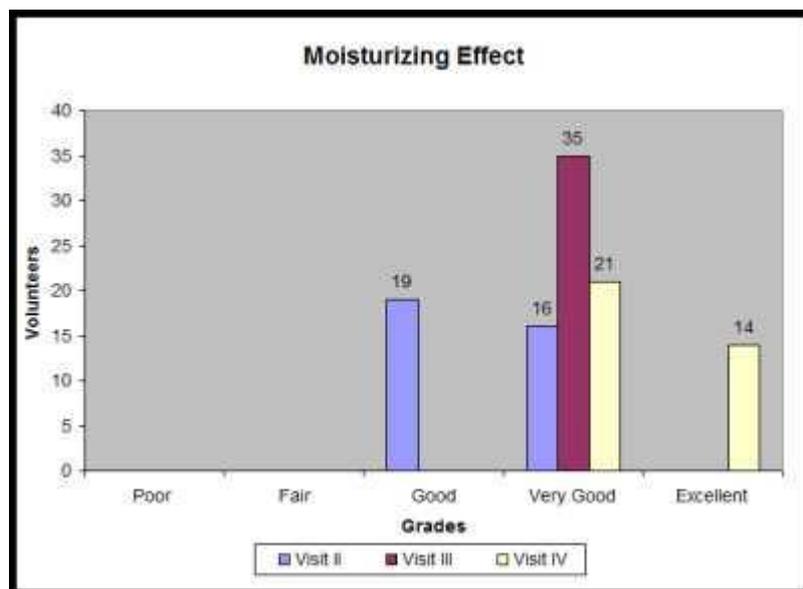
Fig 1

Very good complexion promotion was perceived by 24 volunteers from 2nd week and 34 volunteers from 3rd week and excellent complexion promotion was rated by 12 volunteers at the end of 4th week (Fig 2).



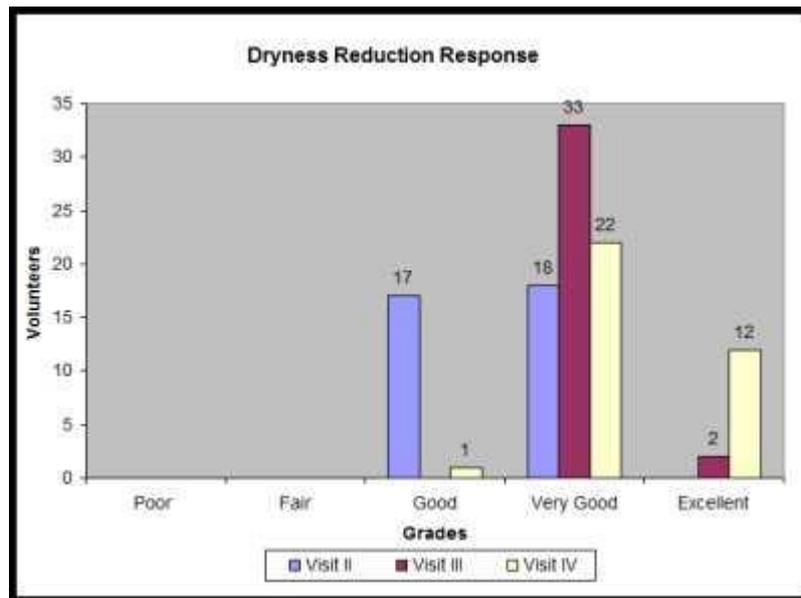
**Fig 2**

Very good moisturizing effect was noticed in 16 volunteers during the 2nd week, all 35 volunteers by the 3rd week and 21 volunteers by the 4th week. Fourteen volunteers rated as excellent by 4th week (**Fig 3**).

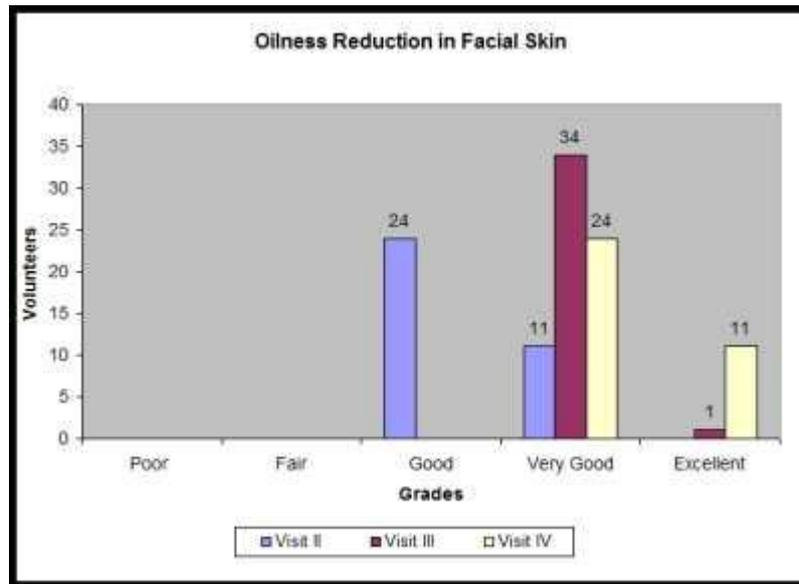


**Fig 3**

Eighteen volunteers perceived very good reduction in dryness by the 2nd week, 33 volunteers by the 3rd week and 22 volunteers by the 4th week. Twelve volunteers have rated excellent reduction in dryness by the 4th week (**Fig 4**). Very good reduction in oiliness was noted by 34 volunteers by the 3rd week while excellent reduction in oiliness was rated by 11 volunteers by the 4th week. (**Fig 5**).

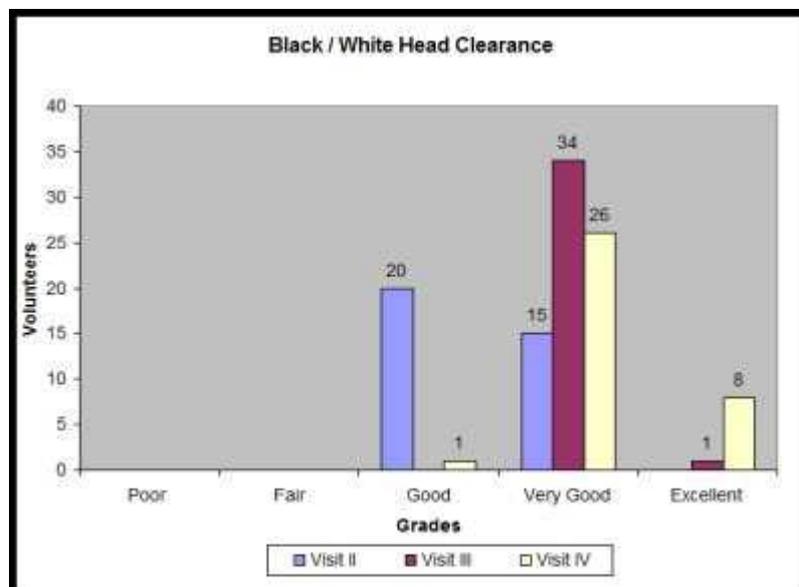


**Fig 4**



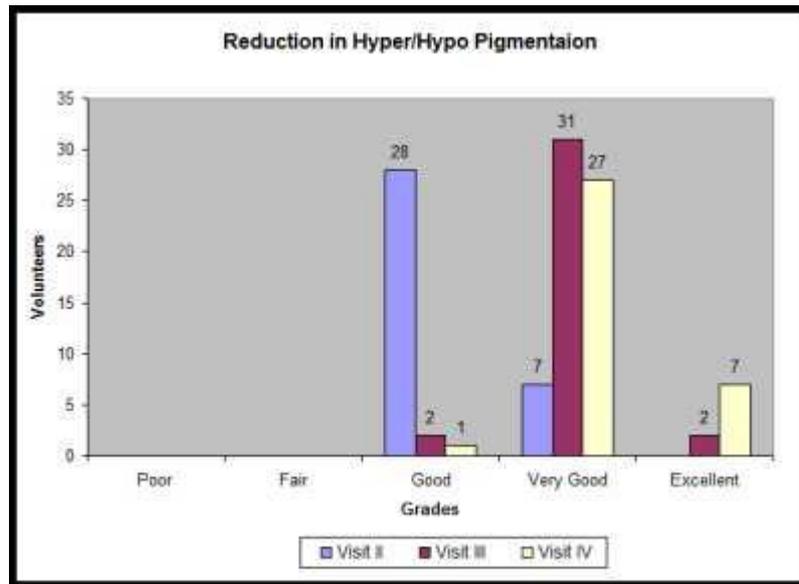
**Fig 5**

Black/white heads clearance was observed very good in 34 volunteers by the 3rd week. The 4th week rating ranged from very good to excellent in 35 volunteers (**Fig 6**).



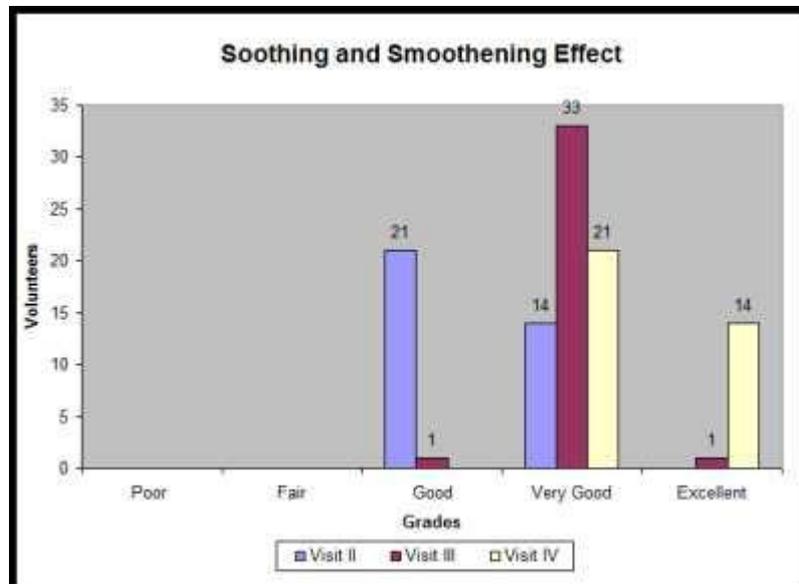
**Fig 6**

Soothing and smoothening effect was very good by the 3rd week and was rated as excellent by 14 volunteers during the 4th week (**Fig 7**).



**Fig 7**

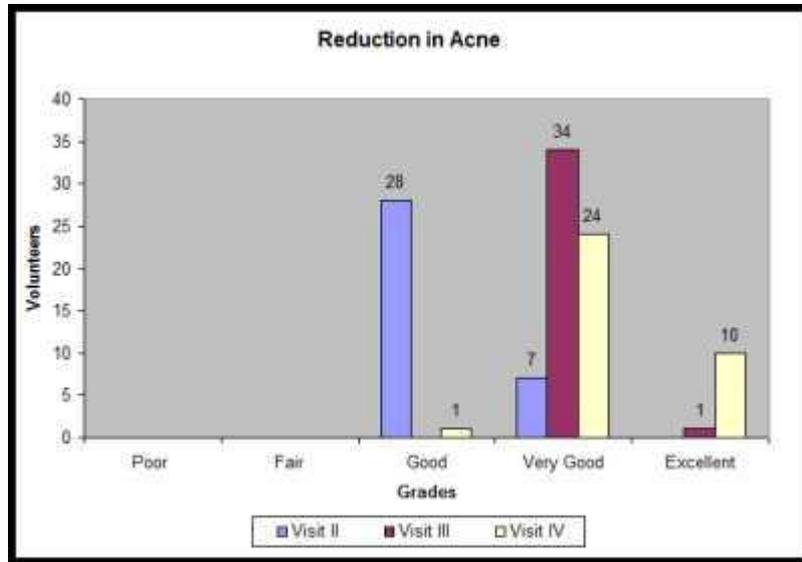
Hyper/hypopigmentation reduction was rated as very good in 31 volunteers during the 3rd week and 7 volunteers rated excellent during the 4th week (**Fig 8**).



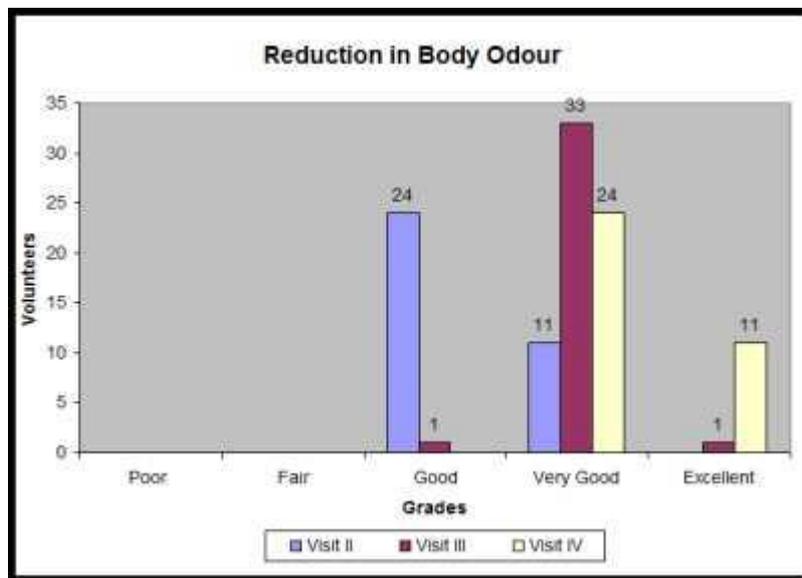
**Fig 8**

Very good acne reduction was observed in 34 volunteers during their 3rd week and excellent reduction perceived by 10 volunteers during the 4th week (**Fig 9**). Very good reduction of body

odor was observed by 33 volunteers by the 2nd week and excellent reduction perceived by 11 volunteers by the 4th week (**Fig 10**).



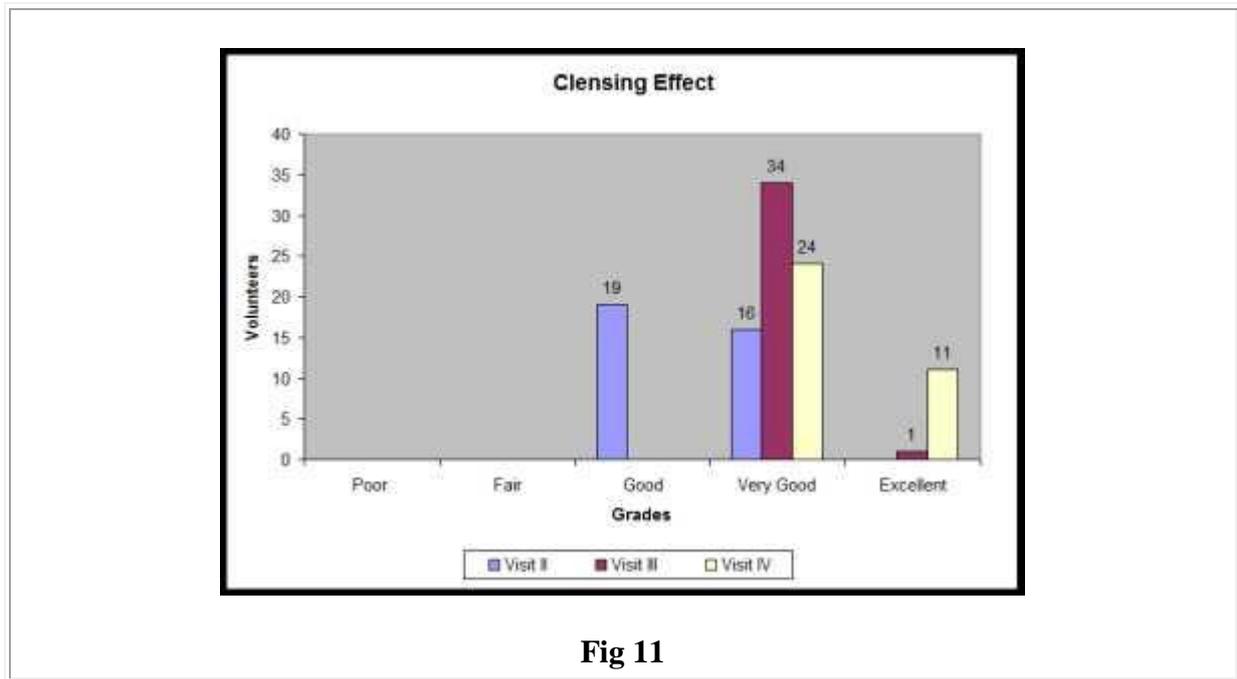
**Fig 9**



**Fig 10**

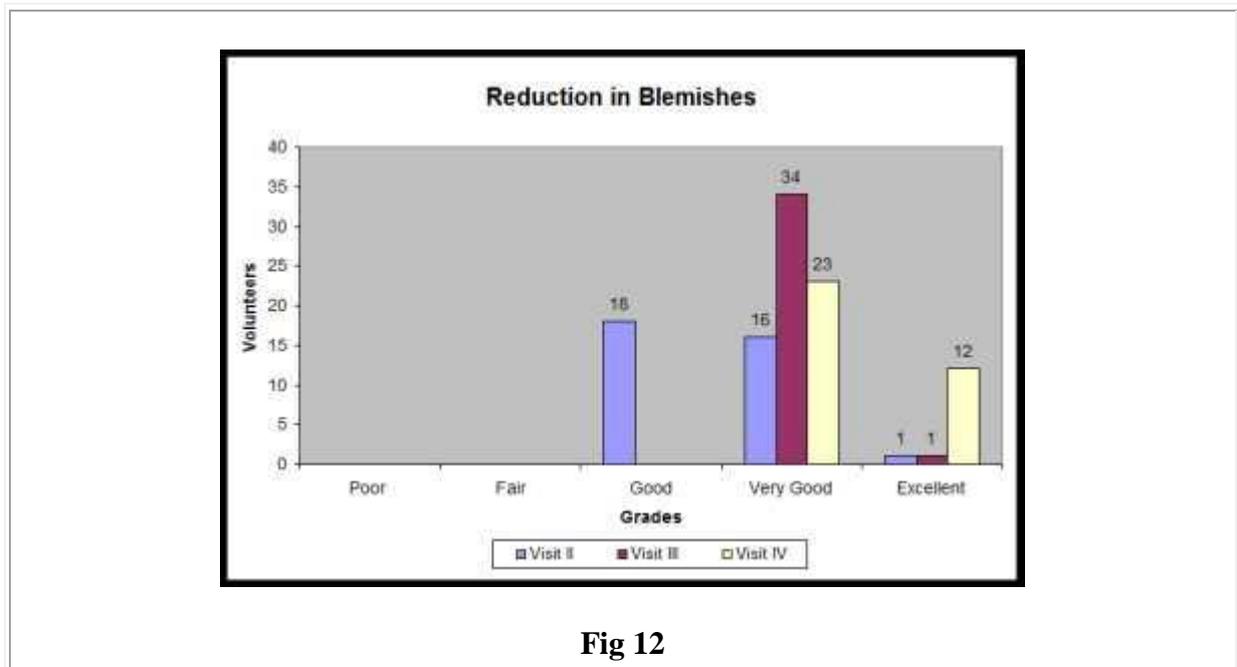
Cleansing effect was perceived by 34 volunteers from the 3rd week rating as very good and 11

volunteers as excellent from the 4th week (**Fig 11**).



**Fig 11**

Blemishes reduction was observed as excellent by 12 volunteers from the 4th week (**Fig 12**). Minimum inhibitory concentration of bathing bar was found to be 1.25 mg/ml against *Malassezia furfur* and *Candida albicans*. The MIC against bacterial cultures *Staphylococcus aureus* and *Micrococcus* species was at 1.25 mg/ml and against *Staphylococcus epidermidis* and *Corynebacterium diphtheriae* was at 2.5 mg/ml (**Table 1**).



**Fig 12**

Organisms	Concentration range (mg/ml)				
	0.62	1.25	2.5	5	10
<i>Staphylococcus epidermidis</i>	+	+	+	-	-
<i>Staphylococcus aureus</i>	+	-	-	-	-
<i>Micrococcus spp.</i>	+	-	-	-	-
<i>Corynebacterium diphtheriae</i>	+	+	+	-	-
<i>Malassezia furfur</i>	+	-	-	-	-
<i>Candida albicans</i>	+	-	-	-	-

- indicates absence of growth

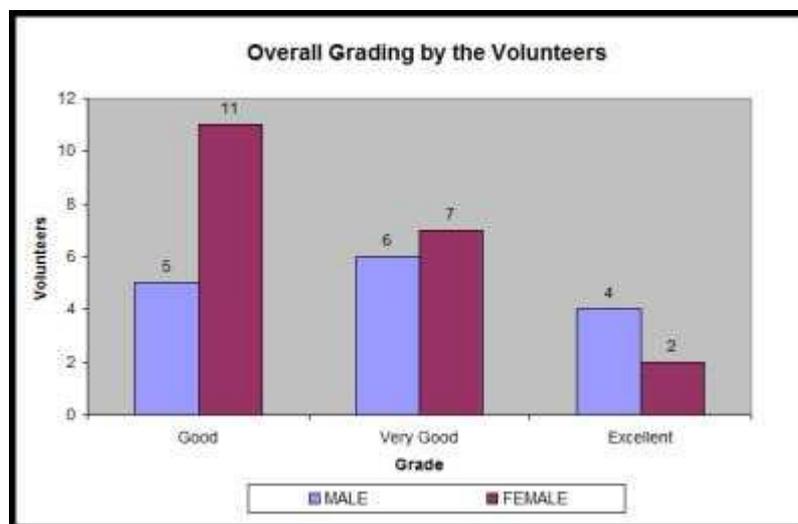
+ indicates presence of growth

**Table 1:** Minimum inhibitory concentration of Medimix Bathing bar with Sandal and Eladi oil against skin pathogens

## Discussion

Medimix bathing bar with Sandal and Eladi oil consists of 46 herbal ingredients which were taken from classical text books which claims the eladi oil gives skin glowing, prevents itching, skin diseases, ringworm, carbuncle and urticaria. Sandal wood oil gives soothing and smoothening effect to the skin and 18 herbs giving protection against skin infections. We have made an attempt to prove this with human volunteers

As per the trial the overall performance of bathing bar rated by volunteers grading 46 % as good, 37 % as very good and 17 % was excellent (**Fig 13**).

**Fig 13**

Our bathing bar is active against the body odor and prickly heat causing bacteria, *Staphylococcus epidermidis* and *Corynebacterium diphtheriae*, showing MIC at 2.5 mg/ml. It is proved experimentally that antibacterial soaps kill the bacteria at a specific concentration; they also have bacteriostatic activity and can inhibit the growth of bacteria. Beauty soaps contain some natural and plant extracted ingredients in their composition which have the ability to inhibit or kill the bacteria so they also gave some bactericidal activity. [5]

Medimix bathing bar with Sandal and Eladi oil could inhibit *M. furfur* and *C. albicans*, the causative organisms for seborrheic dermatitis, pityriasis versicolor and some other skin infections. [6]

A study suggests that the selection of soaps should depend on the working environment. The soap should have good ingredients which have the ability to kill bacteria but not to damage the body tissues. Health care workers should use soaps according to the criteria of Health and Hygiene. Our bathing bar is proven to be effective on the skin without affecting it. Many immuno-compromised or low immunity patients can be protected from the transfer of the pathogenic or opportunistic pathogens by personal hygiene. This area of research requires attention of scientists and people from the soap industry, because the quality of soaps is very important as they are the need of every home. [5]

William Butron, 2009, concluded in a study that pH does not seem to be a significant factor based upon the trends that were observed in the soaps when compared to the soap Irish spring. There is a possibility that at higher concentrations of 0.1 g/ml or higher the pH could be significant. The similarity of the pH levels was considered to be sufficient to demonstrate that the pH was not a significant factor with regard to bacterial inhibition by bar soaps. The primary

support for this conclusion is that the pH of Irish spring soap, which demonstrated no bacterial inhibition, was roughly equivalent to that of Dial antibacterial soap which demonstrated the overall best inhibition of the bacteria tested. In our study we found our bathing bar was showing MIC due to the inhibitory activity of the ingredients and at that concentration their pH was in the range of 6-8 which supports microbial growth in media. [4]

## Acknowledgement

We would like to thank cordially our Managing Directors, Mr. Pradeep Cholayil and Mrs. Jayadevi Pradeep, Cholayil Private Limited, 31A/24, SIDCO Industrial Estate, North Phase, Ambattur, Chennai, Tamil Nadu, India for their support to carry out this project and thank the Team, Apollo hospitals where the clinical trials were carried out.

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