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DESIGN AND DEVELOPMENT OF UNANI EXFOLIATION FACIAL SCRUB (UEFS) FOR SKINCARE

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ABSTRACT

Nowadays revolution comes in the branch of cosmetics, and it has become most popular branch. However, in the modern cosmetic preparations, numerous synthetic chemicals are used which have a lot of side effects. Now, the world is revisiting the herbal heritage for skincare in non-conventional stream of medicine, such as Unani medicine. Natural remedies are more acceptable in the belief that they are safer than the synthetic ones. In Unani system of medicine, there is a broad range of preparations for skincare derived from natural sources. Numerous formulations are mentioned in the Unani classical literature for skincare. The formulations are named as *ghaza*, *ghamra*, *ghaliya*, *ghusool*, *ubtan*, *kohal* etc. But the uses of these formulations in the prescribed dosage forms are not easy as these are time taking and

involve lengthy and laborious procedures for the users. So, there is a need to improve the processing of these dosage forms which can be used easily. There is no formulation available in Unani cosmeceuticals to combat such situations and compete modern cosmetics, such as facial for skin care. Hence, a pharmaceutical strategy has been envisaged to overcome these shortcomings. An innovative approach has been made to formulate, design and develop a user-friendly dosage form for skincare. Thus, Unani Exfoliation Facial Scrub (UEFS) was designed and developed for skincare. The ingredients were selected after an exhaustive search of Unani classical literature. They possess the *jali* (detergent) and *tehseen-e-laun* (complexion enhancer) properties. In the current literature, all ingredients have been reported as having significant anti-microbial and anti-oxidant activity. The UEFS was evaluated by a battery of

physico-chemical tests. Based on the observations and results of the undertaken study, it is concluded that UEFS based on Unani single drugs is a best Unani cosmeceutical formulation for skincare.

KEY WORDS: Unani cosmeceutical formulation, *jali, tehseen e laun*.

INTRODUCTION

It is a well-known fact that non-conventional streams of medicine always played significant role in meeting the global healthcare needs. The World Health organization (WHO) has defined these streams as traditional medicines in terms of "the health practices, approaches, knowledge and beliefs in corporation plant, animal and mineral-based medicines, spiritual therapies, manual techniques and expertise, applied singularly or in combination to treat, diagnose and prevent illness or maintain well being". [1] In India, these systems of medicine are termed as AYUSH, an umbrella of Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy. Historically, these systems are considered to be traditional or Indian in origin or the systems of medicine, which have come to India from outside and got assimilated into Indian culture, are known as Indian Systems of Medicine (ISM). [4]

Unani system of medicine is one of them. Unani system of medicine is based on the knowledge of achieving perfect physical, mental and social health. The primary goal of Unani system of medicine is the maintenance or promotion of good health and prevention or restriction of disease(s). The vast diversity of Unani drug dosage forms (UDDFs) has no parallel in any stream of medicine even in the conventional medicine of today. It is interesting to note that in spite of the popular Unani drug dosage forms (UDDFs), a separate class of UDDFs had also been designed and developed for external use or for the purpose of cosmetic.

The *ashiya-e-muzayyana*/cosmetics are the utility products used extensively throughout the world for maintaining and improving general appearance for face and other parts of body. The concept of maintaining health and beauty, i.e., *Zeenat wa araish* (cosmetics) are also mentioned in the Unani manuscripts and celebrated writings of great Unani physicians, where they wrote about the natural ways and measures for the purpose of cosmetics. Contrary to the common belief that the cosmetics and perfumery belong to the modern times, as a matter of fact, well before the coinage of the word cosmetics, from the Greek language kosmeticos meaning adorn or embellish (for making more attractive, beautiful & decorated) [10], the Arab

physicians had laid foundation of a new branch of knowledge in the form of *Ilm-ul-zeenah* (science of beauty), i.e. nothing but cosmetology.

Nowadays revolution comes in the branch of cosmetics, and it has become most popular branch. However, in the modern cosmetic preparations, numerous synthetic chemicals are used which have a lot of side effects. Now, the world is revisiting the herbal heritage for skincare in non-conventional stream of medicine, such as Unani tib. In Unani system of medicine, there is a broad range of preparations derived from natural sources for skincare. Numerous formulations are mentioned in the Unani classical literature. The formulations are named as ghaza, ghamra, ghaliya, ghusool, ubtan, kohal, khizab, nura, mascara, surma, roghan, marham, tila, zimad etc. But these Unani formulations in the prescribed dosage forms are not easy as these are time taking, and involve lengthy and laborious procedures for the users. So, there is a need to improve the processing of these dosage forms which can be used easily. There is no formulation available in Unani cosmeceuticals to combat such situations, and compete modern cosmetics, such as facial for skin care. Hence, a pharmaceutical strategy has been made to overcome these shortcomings. An innovative approach has been made to formulate, design and develop a user-friendly dosage form for skin care. The present study is based on the design and development of a Unani Exfoliation Facial Scrub (UEFS) for skincare along with its Standard Operating Procedure (SOP).

The concept of *dalk* (massage) in Unani medicine is the most common and widely practiced for restorative, preventive as well as therapeutic purposes. Massage is an oldest practice in medicine, which was used almost all the civilization in the history and evidence of this are present in the several manuscripts.^[3] The Unani Exfoliation Facial Scrub (UEFS) is to be applied on the face and massaged for 4-5 minutes after which it should be wiped off gently by cotton or clean cloth. The scrub exfoliates the dead cell from the upper most layer of skin, i.e., stratum corneum unclogs the pores, removes black and white heads, and cleanses the dirt and dust from the skin. The purpose of this innovative form is to introduce the concept of Unani beautifying agents in the light of modern cosmeceuticals formulations.

MATERIAL AND METHODS

The ingredients of UEFS were procured from Khari Baoli market, old Delhi. These were authenticated by CSIR-NISCAIR, New Delhi. The following ingredients were used in the test formulation:

S. No.	Name of Ingredients	Scientific Name	Part Used
1.	Adas	Lens culinaris	Seeds
2.	Badam talkh	Prunus amygdalus Batsch	Kernel
3.	Baqla	Vicia faba	Seeds
4.	Jao	Hordeum vulgare	Seeds
5	Jaiphal	Myristica fragrance	Fruit
6.	Nukhood	Cicer arietinum	Seeds
7.	Sangtara	Citrus reticulata	Peel

Table 1: List of ingredients included in the UEFS

- **1. Foreign matter separation:** All ingredients were inspected with unaided eyes for the presence of impurities and foreign matter, and which were removed.
- **2. Drying:** All drugs were dried under shade to remove the moisture.
- 3. Preparation of Unani Exfoliation Facial Scrub (UEFS): Before the preparation of UEFS, various brands of scrubs available in the market were surveyed for the determination of base for UEFS. There are many types of bases, namely water base, gel base, cream base etc. used in the synthetic products. However, in the Unani classical literature, any cosmetic formulations for the purpose of skin care has been mentioned in the powder form which has to be applied as paste. Thus, a suitable gel base was selected for incorporation of crude powder of drugs for UEFS.

3.1. Powdering of drugs

- i. All ingredients were taken in equal quantity.
- ii. Before powdering each sample, the mortar, pestle and grinder were properly cleaned.
- iii. All ingredients were pounded in mortar and pestle before grinding.
- iv. All ingredients were powdered in a mixer-grinder and sieved through.
- v. The grinding and sieving was repeatedly done up to complete sieving of powder ingredients.
- vi. Finally, the finished was packed in the sterilized closed container.

3.2 Optimization of Particle Size of Powder of Ingredients of UEFS

All ingredients were grinded with mortar and pestle, followed by mixer-grinder. All ingredients were powdered, and sieved through sieves of different sizes, viz., 120, 100, 80, 60, 40, 30 and 24. All powders were evaluated for their feel or consistency by rubbing between the fingers and over skin of dorsum of hands for grittiness or scrubbing nature. The powder of sieve size No. 30 was found suitable for making scrub in gel base.

4. Optimization and Preparation of gel base

In this study, gel base was prepared by using various gelling agents (Sodium alginate, Chitosan, Carbopol 940). Different concentrations of gel bases with different gelling agents, i.e., 1%, 2%, 2.5% and 3% (w/v), respectively, were prepared, as under

All gelling agents were prepared in 1%, 2%, 2.5% and 3%, concentration, respectively, and concentration of 2% carbopol 940 gel base was found suitable for making UEFS.

Preparation of 2% gel- Two (02) grams of gelling agent was dispersed in 100 ml of distilled water for 24 hours for hydration. Then, it was stirred thoroughly using a magnetic stirrer, and checked for consistency.

5. Mixing of ingredients

- i) Base of 2% carbopol 940 was prepared.
- ii) After 24 hours, the mixture was put on magnetic stirrer for mixing; a thick gel base was obtained.
- iii) Powder of 30 sieve size of UEFS was mixed properly with carbopol 940 gel after continuous stirring for 30 minutes.
- iv) The powder was mixed in 5%.7.5% and 10 % quantities with gel base, respectively.
- v) Gel was found compatible in 5% quantity of powder.
- vi)15% propylene glycol (PG) was added in the formulation as humectants. [2]
- vii) 0.2 % sodium methyl paraban was added as preservative.
- viii) Few drops of essential oil of orange were added for fragrance in the formulation. The prepared face scrub was packed into a well cleaned closed container.^[2]

Table 2: the composition of formulation of UEFS

S. No.	Ingredient	Weight	Ratio
1.	Powder of all the seven ingredients of UEFS of sieve size 30	5 grams	5 %
2.	Gel base of 2 % carbopol 940	100 grams	95 %
3.	Propylene glycol (PG)	15 ml	15 %
4.	Sodium methyl paraban	0.2 grams	0.2 %
5.	Orange essential oil	Few drops	

Evaluation of Physico-Chemical Parameters of Unani Exfoliation Facial Scrub (UEFS)

The prepared final version of Unani Exfoliation Facial Scrub (UEFS) was subjected for the following physico-chemical parameters:

1. Organoleptic Characteristics

- **a. Appearance:** Appearance was recorded according to the consistency whether semisolid or semi-liquid.
- **b. Determination of color:** The color of UEFS was recorded under sunlight.
- **c. Determination of odor:** The UEFS was examined for odor by slow and repeated inhalation of air over the material.
- **d. Homogeneity**, **smoothness**, and **stickiness** were also recorded.

2. Feel and consistency

The feel and consistency of UEFS was noticed by rubbing the formulations between two fingers. Its smoothness or grittiness was also observed and recorded.^[5]

3. Determination of pH

pH of 1% solution- 1 gram of UEFS was dissolved in 100 ml of water, and filtered. The pH was checked with a standardized glass electrode.

pH of 10% solution- 10 grams of UEFS was dissolved in 100 ml of water, and filtered. The pH was determined with a standardized glass electrode. [6]

4. Particle size analysis

This parameter was carried out by using microscope.

5. Determination of Washability

The UEFS was applied on the skin and then ease and extent of washing with water was checked manually.^[2]

6. Determination of Spreadability

Spreadability of UEFS was determined as per method of Muttimer *et al.*, The UEFS (in the quantity of 3 grams each) was placed on this ground plate. The UEFS was then sandwiched between the plate and another glass plate having the dimensions of the fixed ground plate and provided with the hook. One (01) kg weight was placed on the top of the two plates for 5 minutes to expel air and to provide a uniform film between the plates. Excess of UEFS was scrapped off from the edges. The top plate was then subjected to a pull of 50 grams, with the help of a string attached to the hook and the time (in seconds) required by the top plate to cover a distance of 10 cm was noted.^[7]

The Spreadability was calculated using the following formula

S = m. (1/t)

Where,

S = Spreadability 1 = length of the glass slid

t = time m = weight tied to the upper slid

7. Determination of Viscosity

The UEFS was subjected to viscosity study using Brookfield digital viscometer.

8. Determination of Moisture Content

Three grams of UEFS was spread uniformly and thinly in a shallow petri dish and heated at a regulated temperature of 105±1 °C till constant weight and cooled in desiccators, weighed and calculated the percentage loss with respect to UEFS.^[6]

9. Skin Sensitivity / **Patch Test:** The skin sensitivity and non-irritancy of UEFS was evaluated by patch test. It was performed by application on healthy volunteers to evaluate its safety. Though the formulation contained all natural ingredients, which are in use for skincare since long time but for the safety point of view, the following three parameters were done, i.e., primary irritation test, delayed hypersensitivity, and photo irritation or photo allergy.^[8]

Primary irritation

In this test, 20 healthy human volunteers were selected. Definite quantity of UEFS was applied on the forearm region. Prior to the application, any signs of irritation observed were noted. No visible reaction or erythema or intense erythema with edema and vesicular erosion occurred. Both formulations were evaluated by same procedure and possible reactions with different degrees like -No Irritation, + Mild irritation, ++ Moderate irritation, +++ High irritation. [8]

Delayed hypersensitivity

Delayed hypersensitivity test was performed with the same procedure as in primary irritation test by increasing the application time and observation time. After washing of scrub from the skin the reactions were measured for 2 hours of time and noted down.^[8]

Photo irritation/ Photo allergy: Some ingredients may produce an allergic reaction only when exposed to light. This test was aimed to know the possible photo allergic reactions of the prepared UEFS on exposure to sun light on application. Both the formulations were

applied as in the Primary irritation test and the individuals were asked to expose themselves for sun light and possible reactions in the terms of itching, allergy, irritation and signs of redness after washing was measured and noted down.^[8]

10. Stability Study

The stability / shelf life study of UEFS was also carried out at room temperature by visually examination for appearance, odor, consistency and contamination at the interval of 24 hours. Then, weekly observation was done for visual changes up to the period of 6 months.

11. Determination of Microbial Load

UEFS was evaluated for total bacterial count, total fungal count, presence of *E. coli, Salmonella, S. aureus* and *pseudomonas*.

RESULT AND DISCUSSION

The Unani Exfoliation Facial Scrub (UEFS) was formulated through different gelling agents with different sieve size powder. The final preparation of UEFS in 2% carbopol 940 and sieve size 30 was finalized as it was found most suitable and appropriate formulation for UEFS.

It had all characteristics of a standard gel form for facial scrub for local application, such as appearance, smoothness, homogeneity, stickiness, elegancy, pH, spreadability and viscosity. The UEFS gel prepared was light brown in colour. Its smoothness, homogeneity and odor made it more user-friendly. Organoleptic characteristics of prepared UEFS were found to be of a standard formulation.

Table 3: Organoleptic Characteristics of UEFS

Organoleptic characteristic UEFS		Organoleptic characteristic	UEFS
Appearance	Gel	Homogeneity	Homogenous
Color	Light Brown	Smoothness	Smooth
Odor	Orange like	Stickiness	Moderately sticky

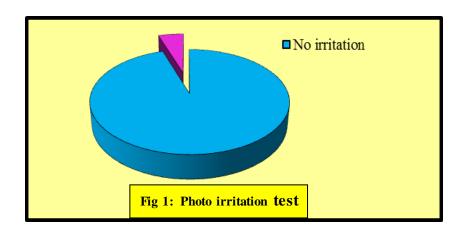
The feel of the UEFS was smooth and grittiness was notices by rubbing the formulation between two fingers. The formulation was sticky and not freely flowed when poured on floor. The washability was found good. The particle size of UEFS was found to be less than 100 micron.

The mean values of pH of the prepared UEFS in 1% and 10% solutions were found to be 6.75

 \pm 0.14 and 6.93 \pm 0.2, respectively, which was in well accordance with the pH (4-7) of skin. The mean values of spreadability (18.1 \pm 1.15 g.cm/ sec), viscosity (2436 \pm 3.605 cps), and moisture content (91.3 \pm 0.754 %) were all in good accordance to a standard gel for local application purpose.

S. No.	pH (1%)	pH (10%)	Spreadability (g.cm/sec)	Viscosity (cps)	Moisture Content (in %)
1.	6.91	7.15	19.3	2439	91.2
2.	6.72	6.89	18	2432	92.1
3.	6.64	6.74	17	2437	90.6
Mean ± SD	6.75 ± 0.14	6.93 ± 0.2	18.1 ± 1.15	2436 ± 3.605	91.3 ± 0.754

Table 4: pH, Spreadability, Viscosity and Moisture Content of UEFS



In skin sensitivity/ patch test during primary irritation test and delayed hypersensitivity test out of 20 individuals no one showed any sign of irritation. In photo irritation test only one individual showed mild irritation. It highlights that the formulation is safe for use as maximum individuals showed no irritation on its application.

Table 5: Result of Patch Test of UEFS

S. No.	Name of test	Number of volunteers	Result	S. No.	Name of test	Number of volunteers	Result
1.	Primary irritation Test	20	No irritation (-)		Photo	19	No irritation (-)
2.	Delayed hypersensitivity test	20	No irritation (-)	3.	irritation test	01	Mild irritation (+)

The stability / shelf life study of the prepared UEFS was also carried out for six months to evaluate any physico-chemical change. No change in colour and odor was noticed in it. A little change in pH of 1% solution was noticed in after 6 months, changing from 6.72 to 6.31, and no contamination occurred in it after 6 months.

Table 5: Stability study of UEFS

S. No.	Weeks	Appearance	pH (1%)	Odor	Contamination
1.	0	Light Brown	6.72	Orange like	Negative
2.	1	Light Brown	6.72	Orange like	Negative
3.	2	Light Brown	6.56	Orange like	Negative
4.	4	Light Brown	6.46	Orange like	Negative
5.	12	Light Brown	6.37	Orange like	Negative
6.	24	Light Brown	6.31	Orange like	Negative

The microbial load showed the total bacterial count (3050 microorganism / gram), total fungal count, *E. coli*, *Salmonella*, *pseudomonas* and *S. aureus* were absent per gram. It is suggested that the prepared UEFS was physico-chemically stable, and possessed characteristics of a standard cosmeceutical formulation for skincare.

Table 6: Microbial Load of UEFS

Test	Result
Total Bacterial Count	3050 microorganism / gram
Total Fungal Count	Absent / gram
E. coli	Absent / gram
Salmonella	Absent / gram
S. aureus	Absent / gram
Pseudomonas	Absent / gram

CONCLUSION

The undertaken study was chosen as there is a felt-need of the hour to design and develop the Unani cosmeceutical formulation as a safe, effective and user-friendly, i.e. Unani Exfoliation Facial Scrub (UEFS). Further, its standardization was carried out after evolving of Standard Operating Procedure (SOP) which is not available at present.

A lot of cosmeceutical formulations available in the market for skincare, but they all contain harmful chemicals. The Unani medicine provides a succor to this situation. Almost all Unani pharmacopoeias mention a number of cosmeceutical formulations for skincare.

The main hindrance in getting the desired therapeutic efficacy of Unani cosmeceutical formulations and its reproducibility is absence of the physico-chemical data and standard operating procedure (SOP) of this conventional dosage form.

In view of this situation, the standard operating procedure (SOP) and its development into an innovative form has been carried out.

708

The Unani Exfoliation Facial Scrub (UEFS) was design and developed in the light of modern cosmeceutical formulations. The scrub exfoliates the dead cells from the upper most layer of skin, i.e., stratum corneum, unclogs the pores, removes black and white heads and cleans the dirt and dust from the skin and improves the complexion and texture of skin.

Besides its exalted position in the classical Unani literature, the Unani cosmeceutical formulations in its existing dosage form has many shortfalls, especially in its application, desired efficacy and shelf life/stability. These disadvantages lead to non-availability of this product in the open market, thus, depriving the people from a time tested, effective and harmless cosmeceutical formulation.

Keeping in view the aforementioned situation, a pharmaceutical strategy was devised to develop, its modified form as Unani Exfoliation Facial Scrub (UEFS), converting all shortcomings into advantages with standard operating procedures (SOPs).

The physico-chemical parameters for standardization of UEFS were done. It had all characteristics of a standard gel form for facial scrub for local application, such as appearance, smoothness, homogeneity, stickiness, elegancy, pH, adhesiveness, spreadability and viscosity.

Further, a clinical study is warranted to evaluate therapeutic efficacy and safety of the newly designed and developed formulation. This would fill the gap of evidence-based Unani therapeutics as well as pharmaceutics.

CONFLICT OF INTEREST: None.

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709

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