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CONVERSION OF A UNANI PHARMACOPOEIAL ANTI-ACNE DRUG “ZIMAD-E-MUHASA” INTO A GEL FORM TO IMPROVE ITS TOPICAL APPLICATION

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ABSTRACT

Zimad-e-Muhasa is a Unani Pharmacopoeial formulation topically used for Acne treatment. In a randomized controlled clinical study conducted at Jamia Hamdard, New Delhi during 2017-2018, *Zimad-e-Muhasa* has shown a significantly higher efficacy than benzyl peroxide 5% gel. However, the application of *Zimad-e-Muhasa* was cumbersome due to its coarse texture and preparation complexity resulting in poor compliance. To improve its topical application and patients' compliance, *Zimad-e-Muhasa* was converted and formulated into a topical gel form by dissolving Carbopol 934, combining it with hydroalcoholic extracts of all the ingredients of *Zimad-e-Muhasa*, and adjusting the pH with Triethanolamine. The physicochemical properties and stability of the herbal gel were assessed, and consistent pH, odour, spreadability, viscosity, microbial growth, and heavy metal content over six months were observed.

Optimal consistency and stability were achieved with 2.5% Carbopol 934, maintaining form and spreadability without liquefying or becoming too thick. The gel's near-neutral pH ensured skin compatibility, and stability tests confirmed its robustness.

A 2.5% concentration of Carbopol 934 produced a stable, uniform, and adequately spreadable gel with a pH close to neutral, ensuring skin compatibility and minimal irritation.

Keywords: *Zimad-e-Muhasa*; *Anti-acne Pharmacopoeial drug*; *Unani topical drug*,
Azadirachta indica; *Abrus precatorius*; *Albizia lebbek*

1. INTRODUCTION

Acne vulgaris, a prevalent condition affecting over 5 billion individuals worldwide, ranks as the 8th most common illness. Its impact extends beyond physical manifestations, encompassing significant implications for an individual's well-being, including psychological and social aspects[1-4]. For decades, antibiotics have been used to treat acne vulgaris, yet antibiotic resistance has been steadily rising in dermatology. To address this growing issue, medicinal plants have been extensively researched as potential alternative treatments [5]. In a clinical study conducted in 2017-2018 at Jamia Hamdard, New Delhi, researchers compared "*Zimad-e-Muhasa*," a Unani Pharmacopoeial formulation, with benzyl peroxide 5% gel for treating acne vulgaris. *Zimad-e-Muhasa* showed a 77.3% reduction in GAGS score ($p < 0.0001$), while benzoyl peroxide showed a 69.8% reduction ($p < 0.0001$), indicating significant improvement in both groups. *Zimad-e-Muhasa* was found to be at least 7% more effective, but patient compliance was challenging due to its coarse texture and preparation complexity [6]. To improve its topical application and patients' compliance, *Zimad-e-Muhasa* was

converted and formulated into a topical gel form in Pharmacognosy and Phytochemistry Lab of Centre of Excellence for Unani Medicine, Jamia Hamdard, New Delhi. This formulation combines a synergistic blend of beneficial components, including hydroalcoholic extracts derived from *Azadirachta indica* leaves, seeds of *Abrus precatorius*, root of *Iris ensata*, bark of *Albizia lebbek*, and *Lake* salt. Additionally, *Aloe barbadensis*, an Unani herbal ingredient, has been incorporated to optimize consistency and enhance efficacy. These compounds have been found to possess antimicrobial [7-12], anti-inflammatory [8, 9, 13-16], and antioxidant properties [7, 9, 12, 14, 17] which have been documented in several studies.

2. MATERIALS AND METHODS

Carbopol 934, Methyl paraben, Propyl paraben, Sodium metabisulphite, and Triethanolamine were procured from Amplicon Biotech (New Delhi, India). The hydroalcoholic extracts of *Azadirachta indica*, *Abrus precatorius*, *Iris ensata*, and *Albizia lebbek* were obtained from Vital Herbs (New Delhi, India). The *Aloe vera* (*Aloe barbadensis*) plants were sourced

from the Herbal Garden at Jamia Hamdard, Hamdard University, Delhi.

3. Development of Formulation

The process of formulating involved a scrupulous and methodical approach to achieve the best possible formulation. To provide a comprehensive understanding of

the ingredients used in the formulation batches, **Table 1** presents a detailed overview. The table encompasses vital information such as the specific ingredients utilized, their corresponding quantities, and any other pertinent details that contribute to the formulation's effectiveness.

Table 1: Composition of Developed Formulations

Batch No	Aloe extract (ml)	Azadiracta Indica extract (g)	<i>Albizia lebbek</i> extract (g)	<i>Iris ensata</i> extract (g)	<i>Abrus Precatorius</i> extract (g)	Lake salt extract (g)	Methyl Paraben Sodium (g)	Propyl Paraben Sodium (g)	Sodium Metabisulphate (g)	Carbopol 934 (g)	Triethanolamine (ml)	Purified water (ml)
F1	75	0.8	0.8	0.8	0.8	0.8	0.020	0.002	0.200	1	1.2	Qs to 100
F2	75	0.5	0.5	0.5	0.5	0.5	0.020	0.002	0.200	1	1.2	Qs to 100
F3	75	0.8	0.8	0.8	0.8	0.8	0.020	0.002	0.200	2	1.5	Qs to 100
F4	75	0.5	0.5	0.5	0.5	0.5	0.020	0.002	0.200	2	1.5	Qs to 100
F5	75	0.8	0.8	0.8	0.8	0.8	0.020	0.002	0.200	2.5	1.8	Qs to 100
F6	75	0.5	0.5	0.5	0.5	0.5	0.020	0.002	0.200	2.5	1.8	Qs to 100
F7	75	0.8	0.8	0.8	0.8	0.8	0.020	0.002	0.200	3	2.1	Qs to 100
F8	75	0.5	0.5	0.5	0.5	0.5	0.020	0.002	0.200	3	2.1	Qs to 100

3.1. Preparation Of *Aloe vera* extract

Thick, luscious, robust leaves of *Aloe vera* (*Aloe barbadensis*) plant were acquired from Herbal Garden, Jamia Hamdard, Hamdard University, Delhi. These leaves underwent a meticulous process to extract the inner part of *Aloe vera*. First, the leaves were collected and thoroughly washed with water, ensuring cleanliness. To guarantee hygiene, they were also treated with a mild chlorine solution. Subsequently, the leaves were sliced horizontally into sections, revealing the inner part known as *Aloe vera* extract. This extract, commonly referred to as the mucilaginous jelly, originates from the parenchyma, which is the central region of the leaf.

Carefully, the thick outer skin was delicately peeled away using a vegetable peeler, exposing the gel-like pulp nestled within the leaf's core. The pulp was then scooped out with a spoon, finely chopped, and homogenized using a blender. To refine the extract further, a Whatman filter paper was employed to filter any impurities. Finally, the filtered *Aloe vera* extract was meticulously preserved in a sterilized, pristine jar, ensuring its quality and longevity.

3.2. Procedure

To prepare the Muhasa Gel, we followed a specific procedure. Firstly, the gelling agent, Carbopol 934 (2.5 g), was dissolved in 10 ml of distilled water. Continuous stirring was maintained at room temperature for an hour

until the gelling agent swelled completely, ensuring proper dispersion. In a separate container, specific amounts of sodium metabisulfite (0.2g), methylparaben sodium (0.02g), and propylparaben sodium (0.002g) were dissolved in 5ml of water. Subsequently, this solution was combined with the gelling agent, resulting in a uniform mixture.

To ensure accuracy, a separate container was employed to measure precisely 75ml of Aloe vera extract. Simultaneously, the herbal hydroalcoholic extracts, weighing 2.5g, were carefully measured, combined,

and thoroughly blended. The resulting combination was added to the Carbopol mixture, and thorough stirring was employed to achieve proper integration. To adjust the pH of the dispersion, Triethanolamine (1.8ml) was added drop by drop while continuously stirring. This step ensured the desired pH level. As a result of this process, a firm gel was formed. Water was gradually added to create the desired volume of the gel, and continuous swirling was maintained to achieve a homogeneous consistency throughout [18].

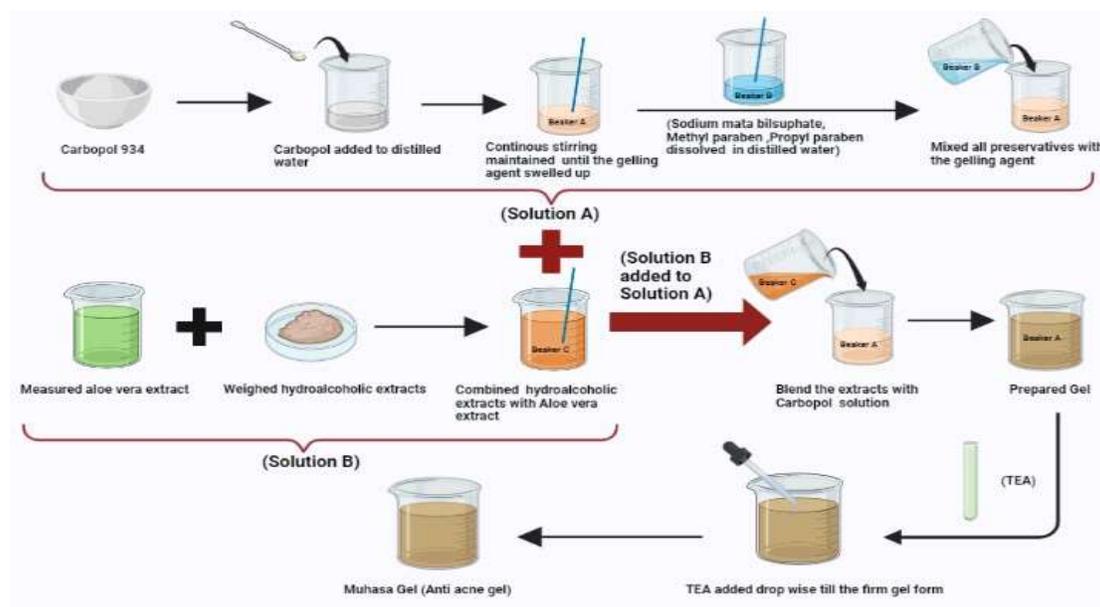


Figure 1: Procedure of formulation

4. Characterization of formulation

4.1. Physical evaluation: Physical parameters such as color, appearance, and consistency were assessed visually to ensure accuracy. This method of evaluation allowed for a more precise and reliable assessment of the product's quality [19].

4.2. Measurement of pH: The pH level of the gel is a critical factor that can influence the skin's barrier function, hydration, and overall health. An optimal pH range of 4-6 is recommended to maintain skin health and avoid irritation. Accurately weighing 1.0 g of gel, it was dispersed in 100 ml of purified

water. The pH of the dispersion was then measured using a digital pH meter, which had been calibrated with standard buffer solutions at 4.0, 7.0, and 9.0. The measurements were taken in triplicate and the average values were calculated [18].

4.3. Homogeneity: The homogeneity of the gel can significantly influence its texture and ease of application. To ensure that the product meets the desired standards, the homogeneity of the gel should be optimized for a smooth, comfortable feel that stays on the skin without dripping. Visual inspection of the developed formulations was conducted after the gel had been filled into the container to evaluate their appearance and detect any aggregates, inconsistencies, clumps, or discoloration [18].

4.4. Grittiness: The gel underwent a thorough analysis, and no grit was detected. This indicates that the gel is of superior quality and is free of any abrasive particles. A lack of grit can help keep your skin feeling soft and supple, while also reducing the risk of skin irritation and other skin-related issues [20].

4.5. Washability: This parameter is essential as some anti-acne gels may leave a residue on the skin, which can block pores and potentially worsen acne. To evaluate the ease and extent of washing off with water, formulations were applied to the skin and then assessed manually [19].

4.6. Spreadability: Achieving optimal characteristics in a topical formulation involves various factors, among which spreadability holds significant importance. Spreadability refers to the capacity of a formulation to be seamlessly applied onto the skin or the affected area. The effectiveness of the formulation's therapeutic properties is closely tied to its ability to spread evenly. To quantify the spreadability of a formulation, a sample weighing 1 gram, prepared 48 hours before the test, is positioned between two glass plates measuring 20 x 20 cm. A weight ranging from 50 to 500 grams, typically 125 grams, is gently placed on top for one minute. Subsequently, the observed increase in diameter resulting from the gel's spreading action is recorded [21, 22].

Spreadability is computed using the following formula:

$$S_i = d^2 \times \pi/4$$

S_i —spreading area (mm^2) depending on mass, d —spreading area diameter (mm)

4.7. Viscosity: The viscosity of the formulations was determined as such without dilution by RHEOPLUS MCR101 (School of Pharmaceutical Education & Research) using spindle#C 20 [18].

5. RESULTS

5.1. Physicochemical evaluation

The physicochemical properties of the herbal gel were assessed and are presented in the **Table 2** below.

5.2. Stability of Gel

Below is the **Table 3** presenting the results of Batch 6 obtained from the Standard Analytical Laboratory (Standard Analytical

Laboratory PVT. LTD, Delhi, India) which were conducted to evaluate the stability of the gel.

Table 2: Physiochemical Properties

S. No.	Parameter	F3	F4	F5	F6	F7	F8
1	Colour	Dark Brown	Light Brown	Dark Brown	Light Brown	Dark Brown	Light Brown
2	Odour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
3	Consistency	Soft	Soft	Moderate	Moderate	Thick	Thick
4	PH	5.82±0.02	6.51±0.03	5.65±0.08	6.01±0.01	5.25±0.0	4.53±0.27
5	Washability	Good	Good	Good	Good	Fair	Fair
6	Spreadability (mm ²)	4035.16±162	3559.7±70.1	3084±86.4	2776.09±29.9	2015.35±26.4	1673.42±32.0
7	Viscosity (Pa.s)	5.7±0.05	6.8±0.02	8.07±0.01	8.78±0.02	9.05±0.01	10.3±0.14
8	Homogeneity	Fine	Good	Good	Good	Poor	Poor

Table 3: Stability of Gel

Chemical parameters						
	pH value	Odour	Nominal weight	Spreadability	Viscosity (Shear rate 50)	
Initial	5.89	Characteristics	100g	2985.3mm ²	4.598 Pa.s	
After 1 month	5.92	Characteristics	100g	2975.6mm ²	4.602Pa.s	
After 3 months	5.90	Characteristics	100g	3015.7mm ²	4.605Pa.s	
After 6 months	5.85	Characteristics	100g	3090.2mm ²	4.608Pa.s	
Test for Aflatoxins						
	B1		B1, B2, G1, G2			
Test Limit	NMT 2 ppb		NMT 5 ppb			
Initial	Not detected		Not detected			
After 1 month	Not detected		Not detected			
After 3 months	Not detected		Not detected			
After 6 months	Not detected		Not detected			
Microbial Contamination						
	Total Bacterial Count cfu/ml	Total Yeast & Mould Count cfu/ml	S.aureus/ml	Pseudomonas Aeruginosa/ml	Salmonella spp./ml	E.Coli/ml
Test Limit	NMT 10 ³	NMT 10 ³	Absent	Absent	Absent	Absent
Initial	<10	<10	Absent	Absent	Absent	Absent
After 1 month	<10	<10	Absent	Absent	Absent	Absent
After 3 months	25	<10	Absent	Absent	Absent	Absent
After 6 months	45	<10	Absent	Absent	Absent	Absent
Heavy Metals						
	Lead, ppm	Arsenic, ppm	Mercury, ppm		Cadmium, ppm	
Test Limit	NMT 10	NMT 3	NMT 1		NMT 0.3	
Initial	BLQ (LOQ 1.0)	BLQ (LOQ 0.5)	BLQ (LOQ 0.5)		BLQ (LOQ 0.1)	
After 1 month	BLQ (LOQ 1.0)	BLQ (LOQ 0.5)	BLQ (LOQ 0.5)		BLQ (LOQ 0.1)	
After 3 months	BLQ (LOQ 1.0)	BLQ (LOQ 0.5)	BLQ (LOQ 0.5)		BLQ (LOQ 0.1)	
After 6 months	BLQ (LOQ 1.0)	BLQ (LOQ 0.5)	BLQ (LOQ 0.5)		BLQ (LOQ 0.1)	

The gel's stability was assessed using various parameters such as viscosity, pH,

Odor, Spreadability, Viscosity, Microbial growth and Heavy metals. The results

indicate that the gel exhibited a stable Viscosity and Spreadability, characteristics Odor, optimal pH level, and no microbial growth.

6. DISCUSSION

The gelling agent plays a vital role as a key ingredient in the formulation. The concentration of the viscosity enhancer or gel former holds immense significance in achieving the desired product characteristics. Through meticulous experimentation, various concentrations of carbomer 934 were tested in Muhasa gels. It was observed that a lower concentration of 1.0% resulted in a very thin consistency, causing the gel to liquefy within 4 hours of preparation. This low concentration failed to provide the desired viscosity, leading to challenges in achieving an even distribution of the active drug and difficulties in handling the gel. Increasing the gelling agent to 2.0% improved the texture of the gel, but liquefaction after 18 hours became evident. However, a gel formulated with 2.5% carbomer 934 achieved a uniform, non-sticky, and smooth consistency that maintained its form without liquefying over time. The gel exhibited excellent stability and demonstrated the desired characteristics for ease of application and drug delivery. On the contrary, as the concentration of carbomer increased to 3%, the gel became excessively thick and sticky, impeding proper spreadability. This high

concentration resulted in a formulation that was challenging to apply and may have hindered effective drug absorption.

To ensure the formulation's compatibility with the skin and mitigate the risk of irritation, the pH of the gel was carefully evaluated. The gel exhibited a pH value of 6.01 ± 0.01 , indicating its proximity to a neutral pH level. This pH value assures that the formulation can be safely applied without causing any skin irritations. Furthermore, this finding suggests that the selected formulation ingredients did not alter the pH of the gel.

Additionally, the spreadability of the formulation was thoroughly examined, uncovering an inverse relationship between the concentration of the gelling agent and spreadability. As the concentration of the gelling agent increased, the spreadability of the gel decreased. The optimized gel demonstrated a spreadability value of 2776.09 ± 29.9 (mm²), indicating its ability to be effortlessly spread with minimal shear. This outcome ensures that the formulation can be applied smoothly, without excessive runoff, while providing ample wet contact time upon application to the targeted area.

To ensure the overall stability of the gel formulation, further testing was conducted at the renowned Standard Analytical Laboratory (ND) PVT. LTD. This step aimed to validate and confirm the gel's stability, considering its composition,

characteristics, and potential impact on drug delivery.

7. CONCLUSION

In conclusion, the careful selection of the gelling agent concentration was crucial in achieving the desired product characteristics. A gel formulated with 2.5% carbomer 934 demonstrated excellent stability, uniform consistency, and adequate spreadability. Moreover, the gel exhibited a pH value close to neutral, ensuring compatibility with the skin and reducing the risk of irritation. These findings provide valuable insights for the formulation of effective and well-tolerated gel products for various applications.

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