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Comprehensive Evaluation of Commercially Marketed Herbal Creams: Assessing Quality, Efficacy, Safety

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ABSTRACT:

Herbal cosmetics are beauty products that contain herbal ingredients that perform desired physiological actions like healing, appearance smoothing, enhancement, and conditioning. Creams come in contact with skin directly so it is important to evaluate the quality product by using different parameters. The primary goal of this work is to evaluate the various parameters like physical evaluation parameters and physicochemical evaluation parameters like dye test, pH, homogeneity, type of smear, washability, after feel, removal,sensitivity test and irritation test, acid value, safonification value, test for thermal stability, total fatty matter and accelerated stability studies in marketed herbal creams according to BIS standards. The herbal cream samples were procured from the local market and named as samples A, B and C. The pH was found to be 7.4, 7.1 and 6.8 for the samples A ,B and C respectively. The TFM value (in %) was found to be (4.83%, 5.58% and 20.22 %). acid value was found to be (6.2; 7.4 and 9.64 milligrams of KOH per gram of sample). Safonification value was found to be (26.3, 29.56 and 32.76 milligrams of KOH per gram of sample) for samples A, B and C respectively. Among all the samples, sample A was found to satisfactory and samples B and C can be improved by quality using quality raw materials.

Key words: dye test; total fatty matter; type of smear; accelerated stability studies, sensitivity test

INTRODUCTION:

Herbal Cosmetics are beauty products that contain herbal ingredients that perform desired physiological actions like healing, appearance smoothing, enhancement, and conditioning. Cosmeceuticals have been extensively used in personal care systems in recent years, and herbal cosmetics are in high demand. Cosmetics are substances that are applied to the body in order to improve, enhance, clean, and modify look without causing harm to the body's functions or structure.[1] Creams are semisolid emulsions that are administered topically to the skin or mucous membranes. Cream has extremely low yield values and pseudoplastic flow characteristics [2]. Creams are of two types: W/O emulsions and O/W emulsions. In addition to offering soothing properties, a skin cream's main function is to shield the skin from external influences and weather. There are several kinds of creams, including massage, night, vanishing, cleaning, cold, and hand and body creams. [3, 4, 5, 6]

The primary objective of this work is to evaluate the various parameters like physical evaluation parameters and physicochemical evaluation parameters like dye test, pH, homogeneity, type of smear, washability, after feel, removal,sensitivity test and irritation test, acid value, safonification value, test for thermal stability, total fatty matter and accelerated stability studies in marketed herbal creams according to BIS standards.

MATERIALS AND METHODS:

All the chemicals used in this research were of standard analytical or pharmaceutical grade. The herbal cream samples were collected from the local market and named as sample A , sample B and sample C.

Evaluation parameters of herbal creams:

a) **Physical evaluation:** The appearance of the cream was carefully evaluated by examining its color, assessing its fragrance for any distinct or appealing scent, and analyzing its texture to ensure consistency, smoothness, and overall tactile quality. These factors collectively contribute to the cream's visual and sensory appeal, which plays a significant role in consumer perception[7]

b) **Dye test:** this test used to determine the emulsion type. The scarlet red dye and cream are mixed. A glass slide was used to hold a small amount of this mixture, which was then covered with a cover slip and observed under a microscope. In the case where the dispersed globules appear red while the background remains colorless, it indicates that the cream is of the O/W type. Conversely, if the dispersed globules are colorless and the background appears red, it signifies that the cream is of the W/O type.

c) pH: Accurately measure 5±0.01 g of the cream in a 100 ml beaker. Pour 45 ml of water into the beaker and disperse the cream within it. Utilize a pH meter to determine the pH of the suspension at room temperature.[9]

d) Homogeneity: the cream samples were thoroughly assessed by conducting both visual inspections and tactile evaluations. The visual examination focused on detecting any inconsistencies in color or the presence of visible particles, while the tactile evaluation involved gently feeling the cream to ensure a uniform texture and smooth consistency throughout. This dual approach allowed for a comprehensive assessment of the product's uniformity.[10]

e) Type of smear: The skin was closely examined to determine the type of smear that developed after the application of the cream. This process involved observing how evenly the cream spread across the skin's surface, noting whether it left a greasy, oily, or matte finish, and assessing the overall absorption rate. Special attention was paid to the residue or film left behind, as it can significantly impact user experience and product effectiveness.

f) Washability: The skin was carefully treated with the cream samples, ensuring an even application to mimic typical usage. Following a set period of absorption, the effectiveness of water washing was assessed by rinsing the treated areas with water to evaluate how easily the cream could be removed. This step helped determine the cream's resistance to water, its lasting effects on the skin, and whether any residue remained post-washing, which could influence user satisfaction and ease of use in everyday settings.[11]

g) After feel: After a precise amount of cream was applied, the emolliency was assessed to determine the moisturizing effect and how well the product softened the skin. Slipperiness was evaluated by gently rubbing the skin to gauge the level of smoothness and ease of spreadability. Additionally, residue levels were carefully examined to identify any leftover greasiness or film on the skin, which can affect user comfort and product performance.[13]

h) Removal: The effectiveness of the cream was evaluated by thoroughly rinsing it off with tap water, allowing for an assessment of how easily the product could be removed after application. This process helped determine whether the cream left behind any undesirable residue or film, indicating its washability and overall user experience. Special attention was given to how the skin felt post-rinse, including any lingering softness, moisture retention, or greasiness, all of which contribute to the cream's practical effectiveness in daily use.[14]

i) Sensitivity test and irritation test: tests were conducted by applying the cream samples to a 1cm patch of skin on the back of the hand. After application, the treated area was exposed to direct sunlight for a duration of 4-5 minutes to simulate everyday conditions and assess any adverse reactions. The skin was closely monitored for signs of irritation, such as redness, itching, or swelling, which would indicate sensitivity to the product. This procedure helps evaluate the cream's safety for regular use, especially for individuals with sensitive or sun-exposed skin.[15]

j) Acid value: To determine the acid value, a 10 gram sample of the substance is dissolved in a precisely measured 50 ml mixture of alcohol and solvent ether. The solution is then heated slowly under reflux using a condenser until the sample is completely dissolved. Next, 1 ml of phenolphthalein is added to the solution, followed by titration with 0.1 N NaOH. The titration is continued until a faint pink color appears after shaking the solution for 30 seconds.[16] The acid value can be calculated using the formula:

$$\text{Acid value} = (n * 5.61) / w,$$

Where n represents the number of ml of NaOH required and w represents the weight of the substance.

k) Saponification value : Reflux 2 grams of the substance with 25 milliliters of 0.5 normal alcoholic KOH for a duration of 30 minutes. Then, add 1 milliliter of phenolphthalein and immediately titrate it with 0.5 normal HCL.[17]

In this equation: The safonification value is calculated as (b-a)*28.05 /w; The volume in milliliters of the titrant is represented by a; The volume in milliliters of the titrant is represented by b ; The weight of the substance in grams is represented by w.

l) Thermal stability: The thermal stability of the cream was evaluated by exposing it to controlled temperatures of 25°C, 30°C, and 40°C over a set period of time. This assessment aimed to determine whether the cream maintained its consistency, texture, and overall integrity when subjected to varying levels of heat. Changes such as separation, melting, or alterations in viscosity were carefully monitored, as these factors directly impact the product's shelf life and performance under different environmental conditions. This evaluation is crucial for ensuring the cream's reliability in diverse climates.[12]

m) Total fatty matter: Accurately weigh approximately 2 grams of the substance and transfer it into a conical flask. Add 25 milliliters of dilute hydrochloric acid to the flask and insert a reflux condenser. Boil the mixture until the solution becomes completely clear. Transfer the contents of the flask into a 300 milliliter separating funnel and allow it to cool down to room temperature. Rinse the conical flask with 50 milliliters of petroleum ether in 10 milliliter portions. Pour the rinsing into the separating funnel, shake it well, and let the layers separate. Separate the aqueous phase and extract it twice with 50 milliliters of petroleum ether each time. Combine all the ether extracts and wash them with water until they are free of acid, as indicated by a methyl orange indicator solution test. Filter the petroleum ether extracts through a filter paper containing sodium sulfate into a previously dried conical flask, which has been weighed at a temperature of 90 ± 2°C. Wash the sodium sulfate on the filter with petroleum ether and combine the washings with the filtrate. Distill off the petroleum ether and dry the remaining material in the flask at a temperature of 90 ± 2°C until a constant mass is achieved.[18]

The total fatty substance, expressed as a percentage by mass, can be calculated using the formula:

(M1 / M2) * 100,

Where M1 is the mass in grams of the residue and M2 is the mass in grams of the material taken for the test.

n) Accelerated stability studies : In the accelerated stability testing, the cream was subjected to controlled storage conditions, where it was maintained at an elevated temperature of 40±2°C for a duration of 7 days to simulate long-term storage effects. Simultaneously, another set of cream samples was kept at room temperature for the same period to serve as a comparative baseline. The samples were carefully monitored and evaluated on the 0th, 3rd, 5th, and 7th days for any changes in their physical appearance, including texture, color, and overall consistency. Additionally, the pH levels, thermal stability, and any signs of degradation or separation were assessed to determine how well the cream maintained its integrity under these varying conditions. This testing is crucial in predicting the product's shelf life and ensuring its quality over time.

RESULTS AND DISCUSSION:

a) Physical evaluation: the appearance [color, odour, texture, and state] of the samples was observed.

Table 1: Physical evaluation

Sl.no	Samples	Color	Odour	State	Texture
1	A	Slight yellow	Pleasant	Semisolid	Smooth
2	B	Slight white	Pleasant	Semisolid	Smooth
3	C	Slight yellow	Pleasant	Semisolid	Smooth

Discussion: From the above observation all the samples A, B, and C have uniform color, pleasant odour, semisolid state and smooth texture.

b) Dye test: The scarlet dye and creams were combined and labeled as S1, S2, and S3. A small quantity of the mixture was then applied onto a glass slide and examined under a microscope. The type of emulsion was subsequently identified.

Table 2: Dye test

Sl.no	Samples	Sample + scarlet dye	Type of emulsion
1	A	S_1	W/O type
2	B	S_2	W/O type
3	C	S_3	W/O type

Discussion: All the 3 cream samples are observed to be of water in oil type of emulations.

c) pH: 5g of sample is weighed and mixed with 45ml of distilled water. pH of samples A,B and C were determined.

Table 3: pH

Sl.no	Samples	pH			Average
1	A	7.4	7.4	7.4	7.4
2	B	7.1	7.1	7.1	7.1
3	C	6.8	6.8	6.8	6.8

Discussion: The pH of cream samples A, B and C were found to be in the range of 6.8-7.4

d) Homogeneity: Homogeneity of samples A,B and C was tested by visual appearance and touch.

Table 4: Homogeneity

Sl.no	Samples	Homogeneity
1	A	Excellent
2	B	Good
3	C	Good

Discussion: Homogeneity of sample A was found to be excellent and sample B and sample C were good.

e) Type of smear: The analysis of the smear type involved the application of samples A, B, and C onto the skin.

Table 5: Type of smear

Sl.no	Samples	Type of smear
1	A	Non-greasiness
2	B	greasy
3	C	greasy

Discussion: The type of smear that was formed was observed after applying it to the skin for samples A, B, and C. Sample A exhibited a non-greasy texture, while the other samples displayed greasiness.

f) Washability: The washability of Samples A, B, and C was assessed after they were applied to the skin and rinsed with water. The rating scale ranged from 0 to 10 to determine the ease of washing.

Table 6: Washability

Sl.no	Samples	Washability
1	A	10
2	B	7
3	C	8

Discussion: The washability of samples A,B and C were rated and it was in range of 7 -10.

g) After feel: The samples A,B and C were applied, the emolliency, slipperiness, and amount of residue were analyzed.

Table 7: After feel

Sl.no	Samples	After feel
1	A	Emollient
2	B	Emollient
3	C	Emollient

Discussion: All the samples a, b and c had shown emolliency.

h) Removal: The cream was applied and examined by washing it with tap water, and the removal was rated on a scale of 0-10 for samples A, B, and C.

Table 8: Removal

Sl.no	Samples	Removal
1	A	10
2	B	9
3	C	10

Discussion: Removal was easy for all samples.

i) Sensitivity test and irritation test: The skin on the hand was subjected to sunlight for a duration of 4-5 minutes after the application of Samples A, B, and C on a 1cm area.

Table 9: Sensitivity test and irritation test

Sl.no	Samples	sensitivity	irritation
1	A	Not found	Not found
2	B	Not found	Not found
3	C	Not found	Not found

Discussion: The samples A, B and C were non-irritant and didn't show any sensitivity effect.

j) Acid Value: The acid value of samples A, B, and C were determined by dissolving 10 grams of each sample in a precisely weighed 50 ml mixture of alcohol and solvent ether. The flask was then connected to a reflux condenser and heated gradually until the samples were completely dissolved. Next, 1 ml of phenolphthalein was added to the solution and titrated with 0.1 N NaOH. The titration was continued until a faint pink color appeared after shaking for 30 seconds. Finally, the acid value was calculated using the appropriate formula.

Table 10: Acid value

Sl.no	Samples	Acid value (in mg of KOH per gram of sample)			Average (in mg of KOH per gram of sample)
1	A	6.2	6.0	6.4	6.21
2	B	7.1	7.8	7.3	7.4
3	C	9.72	9.2	10	9.64

Discussion: Acid value was observed to the samples and readings were found to be 6.2, 7.1, 9.72 for sample A,B and C respectively.

k) Saponification value: 2 grams of the sample were taken and subjected to reflux with 25 milliliters of 0.5 normal alcoholic KOH for a duration of 30 minutes. Following this, 1 milliliter of phenolphthalein was added and the mixture was titrated promptly using 0.5 normal HCL. The safonification value of samples A, B, and C were determined using the appropriate formula.

Table 11: Safonification value

Sl.no	Samples	Safonification value (mg KOH pergram of sample)			Average (mg KOH per gram of sample)
1	A	26.3	25.7	27	26.3
2	B	28.9	30.2	29.6	29.56
3	C	34.7	32.6	31	32.76

Discussion: Safonification value was found to be 26.3, 28.9 and 34.78 for samples A,B and C respectively.

l) Thermal stability: Thermal stability of Samples A, B and C were measured at 25◦C, 30◦C, 40◦C.

Table 12: Thermal stability

Sl.no	Samples	At 25◦C	At 30◦C	At 40◦C
1	A	No phase separation	No phase separation	No phase separation
2	B	No phase separation	No phase separation	Phase separation color change to colorless

3	C	No phase separation	No phase separation	No phase separation color change observed

Discussion: Thermal stability was observed for the samples and sample A was observed to be stable compared to samples B and C.

m) Total fatty matter: Total fatty matter of samples A, B and C were determined.

Table 13: Total fatty matter

Sl.no	Samples	TFM%			Average
1	A	4.83%	4.22%	3.45%	4.16%
2	B	5.58%	5.78%	5.23%	5.53%
3	C	20.22%	21%	23.37%	21.53%

Discussion: Total fatty matter of the samples was observed to be in the range of 4-21 %.

n) Accelerated stability studies: The samples underwent storage at an elevated temperature of 40±2◦C for duration of 7 days. Additionally, the samples were also maintained at room temperature for the same period. Throughout this time, the samples were closely monitored for changes in physical appearance, texture, color, pH, thermal stability, and degradation on the 0th, 3rd, 5th, and 7th day. Accelerated stability studies were conducted specifically for samples A, B, and C.

Table 14: Accelerated stability studies

Stability studies	A		B		C	
	Initial	**After 7days**	**Initial**	**After 7days**	**Initial**	**After 7days**
state	Semi-solid	Semi-solid	Semi-solid	liquid	Semi-solid	Semi-solid
Texture	Smooth	Smooth	Smooth	Liquid	Smooth	Smooth
Color	Slight Yellow	Slight yellow	Slight white	colorless	Slight yellow	Slight yellow
pH Value	7.4	7.4	7.1	7.5	6.8	7
Thermal Stability	Stable	No phase separation	Stable	Phase separation	stable	No phase Separation, Slight color change
Degradation of product	Nil	nil	nil	observed	nil	observed

Discussion: in the accelerated stability study sample A was found to more stable than that of the sample B and C.

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CONCLUSION:

The study aims to assess the herbal creams that are marketed. The samples (A, B and C) collected from the local market were evaluated according to BIS standards. Among all the samples, sample A was found to satisfactory and samp0les B and C can be improved by quality using quality raw materials.

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