ejpmr, 2025, 12(7), 445-459

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

SJIF Impact Factor 7.065

Review Article

ISSN (O): 2394-3211

ISSN (P): 3051-2573

FORMULATION AND EVALUATION OF *ARGEMONE OCHROLEUCA* EXTRACT CREAM NATURCEUTICAL DELIVERY SYSTEMS AS ANTIMICROBIAL AND WOUND HEALING ACTIVITY

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Article Received on 21/05/2025 **Article Revised on 11/06/2025** **Article Accepted on 01/07/2025**

ABSTRACT

Wounds affect a large number of patients and can seriously reduce the quality of life. The purpose of this study was designed to investigate the phytochemicals and evaluate the antimicrobial agent for wound healing activity of *Argemone ochroleuca* extracts also to formulate the most active extract as oil in water cream (O/W) and evaluate its wound healing activity. The herbal creams (O/W) were formulated from methanolic *Argemone ochroleuca* extract. Four formulations were prepared with various concentration of excipients. The pH, spreadability and stability of prepared base were investigated. The base B4 was found appropriate for the preparation of cream. Completely cream was evaluated for its physical, chemical and stability parameters. Therefore, formulation of methanolic extract into a suitable herbal cream was aimed. The pH of prepared cream was near to skin pH, and cream was homogeneous, non-greasy and easily removed after application. Also, the best formulation for cream selected which Confirmed all the requirement for quality control tests for product and *Argemone ochroleuca* have a potential effect of bioactive methanolic extract that can be used in management of bacterial infection and promote wound healing activity. It was concluded that the best formulation selected F1 (1%) and F2 (2%) were safe in respect to skin irritation and allergic sensitization and exhibited the desired proprieties of consistency, spreadability, physicochemical stability and appearance may make it cosmetically acceptable.

KEYWORDS: *Argemone ochroleuca*, Cream Formulation, Antimicrobial agent, Wound Healing Activity, Nutraceutical Delivery Systems.

INTRODUCTION

Background of *Argemone ochroleuca* (Family: Papaveraceae)[1-89]

A medicinal plant is any plant, which one or more of its organs are contains substances that can be used for therapeutic purposes, or which are precursors for chemo pharmaceutical semi synthesis. When a plant is designated as medicinal, it is implied that the plant is useful as a drug or therapeutic agent or as an active ingredient of a medicinal preparation.

The plant product or natural products show an important role in diseases prevention and treatment through the enhancement of antioxidant activity, inhibition of bacterial growth, and modulation of genetic pathways. The therapeutics role of number of plants in diseases management is still being enthusiastically researched due to their less side effect and affordable properties. It has been accepted that drugs based on allopathy are expensive and also exhibit toxic effect on normal tissues and on various biological activities. It is a largely accepted fact that numerous pharmacologically active drugs are derived from natural resources including medicinal plants.

Plants have been used in medicines since time immemorial. India has a rich heritage of using medicinal plants in traditional medicines, as in the Ayurveda, siddha and Unani systems besides folklore practices. The plant kingdom is a virtual goldmine of biologically active compounds, and it is estimated that only 10-15% of existing species of higher plants have been surveyed.

Many plants have been successfully used in the treatment of various diseases. The ancient record is evidencing their use by Indian, Chinese, Egyptian, Greek, Roman, and Syrian dates back to about 5000 years. History of Argemone Mexicana plant and it Availability Meaning of the name Argemone -argots means white spot, eye cataract, which the plant was believed to cure; mexicana -from Mexico.

The Papaveraceae family consists of annual or perennial herbaceous plants; they can grow in sunny and open environments. This group of plants is composed of approximately 45 genera with more than 400 species commonly distributed in different points of the Northern Hemisphere. Papaveraceae family is included phylogenetically in a group known as "psychoactive families" because of it includes representative plants like *Papaver somniferum* L., "adormidera"; alkaloids such as morphine and heroin have been extracted from them, on the other hand these plants can be cultivated as ornamental plants.

Argemone is a genus of flowering plants in the family Papaveraceae. It contains 30-32 species, commonly known as „Prickly Poppies" all with prickly stems, leaves and capsules.

Morphological Characteristics of Argemone Species

Similar species Argemone mexicana differs from A. ochroleuca in that it has bright yellow flowers as opposed to cream or pale-yellow flowers, and globular flower buds as opposed to the egg-shaped buds of Argemone ochroleuca. The leaves of A. mexicana are green as opposed to bluish glaucous for A. ochroleuca. Cotyledons Cotyledons are linear and pale green, fleshy to acute apex, 6 cm long. First Leaves First leaves are simple, alternate, arranged in a rosette, green ribbed white, sessile. The blade is spatulate, attenuate at base, 6 to 8 cm long and 1 cm wide with 4 strong teeth, terminating ina short spine. As shown in Figure 1.

Plant belong to *Argemone* genus are important medicinal plant. several traditional uses were described from these plants such as expectorant, demulcent, diuretics, emetic and treatment in chronic skin diseases. The chemical characterization of *Argemone* species afforded various metabolites, such as terpenoids, alkaloids, phenolics and flavonoids.

The specie *A. ochroleuca* has been frequently confused with *A. mexicana* by their close biological relationship, because they share similarity phenotypic. One main biochemical characteristic of the genus *A. ochroleuca is* the presence of phytochemicals of great pharmacological importance, for example the alkaloids like Isoquinolines, from where compounds as Alocryptopine, Protopine and Berberine have been isolated and characterized.

Argemone ochroleuca Sweet is Papaveraceae family, known as *"chicalote"*. It is an annual herb, 0.2-1-meter-high with yellow sap, erect stems, pithy, and covered with stiff yellow prickles. *Argemone ochroleuca* Sweet is used to treat eye infection, respiratory and dermatological disorders.

Wounds are major concerns for the patient and clinician alike. Wounds are injuries caused by physical, chemical, and immunological insult to tissue and results in opening or breaking of skin. As wound infection is found majorly in developing country. More than 80% of population was depend on traditional medicine. The World Health Organization (WHO) has also recommended the evaluation of the effectiveness of plants in treatment where we lack safe modern drugs. Approximately one-third of all traditional medicines in use are for the treatment of wound and skin disorders. Wound healing process has several steps *viz*., coagulation, inflammation, and granulation tissue formation, formation of matrix, connective tissue remodeling, collagenization and wound strength acquisition. Wound healing is an important biological process involving tissue repair and regeneration.

Argemone ochroleuca flower is white and often found this in high altitude areas, the leaves are pale green and located almost exclusively in the high-altitude areas such as Yareem, Dhamar, Sanaa and Amran. The season of flowering occurs mostly during spring and summer, but may also occur throughout the rest of the year.

Fig. 1: *Argemone Ochroleuca*.

A. mexicana is an erect prickly annual herb of about 1m high; leaves are usually 5 to 11 cm long; and more or less blotched with green and white, glaucous broad at the base, half-clasping the stem prominently sinuate-lobed, and spiny. The flowers become 4 to 5 cm in diameter, and are terminal, yellow, and scentless. The capsule is spiny, obovate or elliptic-oblong, and about 3 cm in length as shown in Figure 2. The seeds are spherical, shining, black and pitted. *A. mexicana* is widely used in folk medicine to alleviate several aliments especially for analgesic, antibacterial, antimalarial, antispasmodic, sedative and narcotic effect. Seeds are useful in cough an asthma. It used traditionally as antidote to various poisons. The fresh yellow, milky, seeds extract contains protein dissolving substances which are effective in the treatment of warts, cold sores, cutaneous infections, skin diseases, itches and also in dropsy a jaundice. The root has an anthelmintic activity. Leaves of *A. mexicana* are also traditionally used as antiasthmatic. The wide variety of the traditional uses of the plant may be due to the presence of various phytochemicals like alkaloids, amino acids, phenolics, and fatty acids. In Yemen is called baround, snafah, senif, his flower yellow. Annual herbs grow on agricultural Land and fallow land and valley bottoms, such as Taiz, Ibb, Dhamar, Dhale, Maweah, Muwzea, Damt and Socotra.

Fig. 2: *Argemone Mexicana.*

Anatomy of Skin

The skin is the largest organ of the body, accounting for regarding 15% of the overall weight. It performs several very important functions, together with protection against external physical, chemical, and biological assailants, similarly as prevention of excess water loss from the body and a role in thermoregulation. The skin is continuous, with the mucous membranes lining the body's surface. The system is made by the skin and its by- product structures. The skin composed of three layers: the epidermis, the dermis, and subcutaneous tissue. The outermost level, the epidermis, consists of a selected constellation of cells called keratinocytes that perform to synthesize albuminoidal, along, thread like super molecule with a protecting role. The middle layer, the dermis, is fundamentally made up of the febrile structural protein known as collagen. The dermis lies on the connective tissue, or panicles, that contains tiny lobes of fat cells called lymphocytes. The thickness of those layers varies significantly, betting on the geographic location on the anatomy of the body. The eyelid, for instance, has the thinnest layer of the epidermis, measure but 0.1 mm, whereas the thickest stratum layer, measure approximately 1.5mm. The dermis is thickest on overlying epidermis, wherever it's 30–40 times as thick because the suprajacent epidermis. As shown in Figure 3.

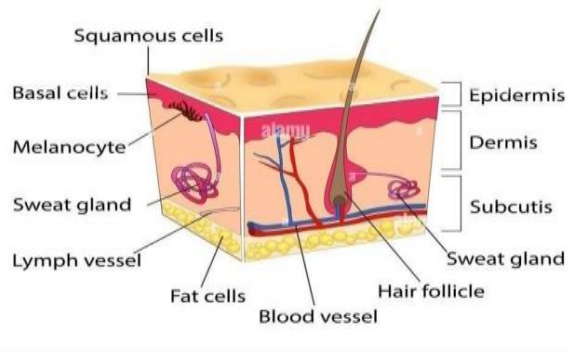

Fig. 3: Skin Structure.

Wound Healing Activity

Wound is defined as disruption of cellular, anatomical, and functional continuity of a living tissue. It may be produced by physical, chemical, thermal, microbial, or immunological insult to the tissue. Wound healing is the process of repair that follows injury to the skin and other soft tissues. Following injury, an inflammatory response occurs and the cells below the dermis (the deepest skin layer) begin to increase collagen (connective tissue) production. Later, the epithelial tissue (the outer skin) is regenerated. Wound healing is the interaction of a complex cascade of cellular and biochemical actions leading to the restoration of structural and functional integrity with regain of strength of injured tissues. It involves continuous cell-cell interaction and cell-matrix interactions that allow the process to proceed in different overlapping phases and processes including inflammation, wound contraction, re-epithelialization, tissue remodeling, and formation of granulation tissue with angiogenesis. The phases of wound healing normally progress in a predictable, timely manner, and if they do not, healing may progress inappropriately to either a chronic wound such as a venous ulcer or pathological scarring such as a keloid scar.

The Four Phases of Wound Healing

It is believed that chronic wounds also undergo 4 basic phases of healing (although some authors combine the first 2 phases). first, Hemostasis; In wound healing, the platelets are the cells that act as utility workers sealing off the damaged blood vessels. The blood vessels themselves constrict in response to injury, but this spasm ultimately relaxes. The platelets secrete vasoconstrictive substances to aid this process, but their prime role is to form a stable clot sealing the damaged vessel. platelets also secrete growth factors such as platelet-derived growth factor, which is recognized as one of the first factors in initiating the subsequent healing steps. These growth factors recruit neutrophils and monocytes

(initiating the next phase of wound healing), stimulate epithelial cells and recruit fibroblasts. Second, Inflammation, this stage usually lasts up to 4 days post injury. The inflammatory response causes the blood vessels to become leaky, releasing plasma and neutrophils into the surrounding tissue. The neutrophils phagocytose debris and microorganisms and provide the first line of defense against infection. As they digest bacteria and debris, neutrophils die and release intracellular enzymes into the surrounding matrix, which further digest tissue. As fibrin is broken down as part of this clean-up, the degradation products attract the next cells involved such as fibroblasts and epithelial cells. They are aided by local mast cells. Third, Proliferation (also known as granulation and contraction) approximately 4 days after wounding and usually lasts until day 21 in acute wounds, depending on the size of the wound and the health of the patient. It is characterized by angiogenesis, collagen deposition, granulation tissue formation, wound contraction and epithelialization. Clinically, proliferation is observed by the presence of pebbled red tissue or collagen in the wound base and involves replacement of dermal tissues and sometimes subdermal tissues in deeper wounds, as well as contraction of the wound. Fourth, Remodeling (also known as maturation) in wound repair, the healing process involves remodeling and realignment of the collagen tissue to produce greater tensile strength. In addition, cell and capillary density decrease. The main cells involved in this process are the fibroblasts. Remodeling can take up to 2 years after wounding. This explains why closed wounds can quickly breakdown if attention is not paid to the initial causative factors.

Semisolid Drug Delivery Systems[90-150]

Semisolid constitute a significant portion of pharmaceutical dosage form. They serve as carriers for drugs that are topically delivered by way of skin, cornea, rectal tissue, nasal mucosa, vagina, buccal tissue, urethral membrane, and external ear lining. Because of their peculiar rheological behavior, semisolid can adhere to the application surface for sufficiently long periods before they are washed off. This property helps prolong drug delivery at the application site.

Semisolids are available as a wide range of dosage forms, each having unique characteristics. Topical semisolid dosage forms are normally presented in the form of creams, gels, ointments, or pastes. They contain one or more active ingredients dissolved or uniformly dispersed in a suitable base and any suitable excipients such as emulsifiers, viscosity increasing agents, anti-microbial agents, antioxidants‟, or stabilizing agents. The advantages of semisolid dosage form are: It is used external, probability of side effect can be reduced, local action, first pass gut and hepatic metabolism is avoided and patient compliance is increased; the drug termination is problematic cases is facilitated as compared with other routes of drug administration. The disadvantage of semi-solid dosage form is; there is no dosage accuracy in this type of dosage form, the base which is used in the semisolid dosage form can be easily oxidized, and if we go out after using semisolid dosage form problems can occur. Semisolid are available as wide range of dosage form, each having unique characteristic.

Creams are the topical preparations which can be applied on the skin. Creams are defined as “viscous liquid or semisolid emulsions of either the oil-in-water or water-in-oil type” dosage forms which consistency varies by oil and water. Creams are used for cosmetic purposes such as cleansing, beautifying, improving appearances, protective or for therapeutic function. These topical formulations are used for the localized effect for the delivery of the drug into the underlying layer of the skin or the mucous membrane. These products are designed to be used topically for the better site-specific delivery of the drug into the skin for skin disorders. Creams are considered as a pharmaceutical product as they are prepared based on techniques developed in the pharmaceutical industry, unmediated and medicated creams are highly used for the treatment of various skin conditions or dermatomes. Creams can be ayurvedic, herbal or allopathic which are used by people according to their needs for their skin conditions. They contain one or more drugs substances dissolved or dispersed in a suitable base. Creams may be classified as o/w or w/o type of emulsion on the basis of phases. Hydrophobic creams (w/o): Hydrophobic creams are usually anhydrous and absorb only small amount of water. They contain w/o emulsifying agent such as wool fat, sorbitan esters, and monoglycerides.

Hydrophilic creams (o/w): Hydrophilic creams contain bases that are miscible with water. They also contain o/w emulsifying agents such as sodium or triethanolamine soaps, sulfated fatty alcohols and polysorbates combined, if necessary, with w/o emulsifying agents. This cream is essentially miscible with skin secretions.

Traditional Use of *Argemone Ochroleuca*[10-89]

The plant is reported to be used as diuretic, purgative, anti-inflammatory, analgesic and believed to destroy worms, cure itching, various skin diseases and an antidote to various poisons. The seeds are purgative and sedative (Ayurveda), useful in skin diseases and leukoderma (Yunani) and in Homeopathy, the tincture of the entire plant is reported to be used orally for bronchitis and whooping cough. The fresh juice of the leaves and the latex, both are reported to be used externally as a disinfectant for open wounds and cuts.

In the 20th century, the National Medical Institute indicates the following uses: antiscorbutic, to treat dental problems, wound healing, and as regenerative, against dermatosis, and eye problems. The flowers, leaves, and juice of the plant are used in some diseases of the eyes and other activities as anticonvulsant, antidiarrheal, antispasmodic, antitussive, cathartic potential, to treat corneal spots, joint diseases, hypnotic, narcotic, and

analgesic.

The present study has been designed to determine the antimicrobial and wound healing activity of *Argemone Ochroleuca* extract *which* has been widely used for these purposes, and to formulate the most active extract as oil-in-water cream for topical application.

MATERIALS AND METHODS

Materials

The extract of *Argemone ochroleuca* was prepared and gift from (Dr. Salwa M. Raweh, Associate Professor Dr. of Pharmacognosy, Department of Pharmacognosy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen).

Methanol 99.9% (Sigma Aldrich, Germany), *n*- hexane (Sigma Aldrich, Germany), ethyl acetate (Sigma Aldrich, Germany) distilled water, chloroform, sulphuric acid, benzene, ammonia, 5% ferric chloride, 10% lead acetate, magnesium ribbon, hydrochloride acid, isopropyl alcohol, stearic acid, cetomacrogol, beeswax, liquid paraffin, methylparaben, and propylene glycol. Media: Mueller Hinton agar plates (Himedia,India), peptone water medium(Himedia, India), antibiotic sensitivity discs (Himedia, India),Muller-Hinton Agar (MHA) (Deben Diagnostics Ltd, UK). Reference drugs: Fucidic acid 2% and Ciprofloxacin 10µg/disc. The microorganism used included gram-positive bacteria *Staph. Aureus*, gram negative bacteria *E. coli* and fungus strain *Candida albicans* from Central Laboratories, Sana'a, Yemen.

Formulation and Evaluation of *Argemone ochroleuca* Extract Creams[65-194]

Performulation Study of *Argemone Ochroleuca*

Prior to the development of dosage forms, it is essential that certain fundamental physical and chemical properties of the drug molecule and other derived properties of the drug powder are determined. This information dictates many of the subsequent events and approaches in formulation development. This first learning phase is known as pre-formulation. Pre-formulation is an important step in the development of a new drug. It influences the safety, effectiveness, controllability, stability, and compliance of the drug.

Solubility Test

Different weights (75mg ,50mg) of *Argemone Ochroluca* extract was dissolved in two different solvents that is water and isopropyl alcohol using two methods manually (shake flask method and instrumentally (by Ultrasonic bath).

pH Determination

About 10 mg of *Argemone Ochroluca* extract was dissolved in 100ml of water, then the PH was measured for 3 times.

Formulation of *Argemone Ochroleuca* Creams

Preparation of Base

The formulation components used were listed in Table 1. Formulation of the cream is started from the cream base (o/w). Four formulations varying in the ingredients and amounts were prepared by emulsification. Oil in water emulsion were formulated. The emulsifier (stearic acid) and other oil soluble components (cetomacrogol, white beeswax, mineral oil) were dissolved in the oil phase (Part A) and heated up to 80° C. Water soluble components (Methylparaben, Propylene glycol, triethanolamine) were dissolved in (Part B) and heated up to 80° C. After heating, the aqueous phase was added in portions to the oil phase with constant stirring until cream is formed.

Table 1: Formulation of Cream Base.

Type of Phase	Ingredients	B1 % w\w	B2 % w\w	B3 % w\w	B4 % w\w
Oil Phase	Stearic acid	2.5	2.5	4.0	1.5
	Cetomacrogol	10	8	8	8
	Beeswax	1.5	0.5	0.5	0.5
	Mineral oil	5.0	5.0	5.0	5.0
Water Phase	Propylene glycol	5.0	5.0	5.0	5.0
	Triethanolamine	2.0	1.75	1	0
	Methylparaben	0.01	0.01	0.01	0.01
	Water	Up to 100	Up to 100	Up to 100	Up to 100

Preparation of Creams

By choosing base B4, oil in water emulsion of 1% and 2% of drugs were formulated as shown in Table 2. The emulsifier and other oil soluble components were dissolved in the oil phase (Part A) and heated up to 80°C. Extract and water-soluble components were dissolved in (Part B) and heated up to 80°C. After heating, the aqueous phase was added in portions to the oil phase with constant stirring until cream is formed.

Table 2: Formulation of Creams.

Type of Phase	Ingredients	F1(1%) W\W	F2(2%) W\W
Oil Phase	Stearic acid	1.5	1.5
	Cetomacrogol	8.0	8.0
	Beeswax	0.5	0.5
	Mineral oil	5.0	5.0
Water Phase	A. ochroluca Extract	1.0	2.0
	Propylene glycol	5.0	5.0
	Methylparaben	0.01	0.01

Evaluation of Cream Formulations
The cream was then evaluated for the following physical parameters.

Formulation Properties
The formulation properties of the cream were studied by visual appearance and characteristics.

Presence of Foreign Particles/Grittiness
A small amount of cream was taken and spread on a glass slide free from grease and was observed against diffused light to check for presence of foreign particles.

pH Determination of Cream
The pH of various formulations was determined by using digital pH meter. About 1 g of the cream was weighed and dissolved in 100ml of distilled water and stored for two hours. The measurement of pH of each formulation was done in triplicate and average values were calculated.

Viscosity Evaluation of Cream
Viscosity off the formulation was determined by Brookfield viscometer II+ model using spindle NO S-4 at 50 rpm at temperature of 25°C.

Stability Studies
Stability studies were performed to check the effect of environmental condition or storage conditions on formulation. However, the studies will take a longer time and hence it would be convenient to carry out the accelerated stability studies where the product is stored under extreme condition of temperature. To assess the drug and formulation stability, this stability study is done. The optimized formulation is sealed in the aluminum packing and various replicates were kept in humidity chamber maintained at 40°C and 75% RH for 30 days. The sample is analyzed for the physical changes, % drug content, cream properties and *in vitro* diffusion study.

Irritancy Test
The cream was applied on specified area of 1sq.cm on dorsal surface of left hand.

Remove Ability
The ease of removal of the cream applied was examined by washing the applied part with tap water.

RESULTS AND DISCUSSION

pH Determination of Cream
The mean of pH of the cream base is (5.8 - 6) with standard deviation ± 0.083SD.

Solubility Test
The result of the solubility as shown in Table 3. Generally, the MeOH extract was soluble in water specially when shake by sonicator. The solubility of MeOH extract *of A. ochroleuca* extract in water using different method of shaking.

Table 3: Solubility of MeOH Extract *A. Ochroleuca* in Distilled Water.

Conc	Shaking by Hand	Shaking by Sonic (10min)	Shaking by Sonic(20min)
75mg	Slightly Soluble with Insoluble Particles	Practically Soluble	Soluble
50mg	Slightly Soluble with Insoluble Particles	Practically Soluble	Soluble

The solubility of MeOH extract of *Argemone Ochroluca* extract in isopropyl using different methods of shaking as shown in Table 4.

Table 4: Solubility of MeOH Extract *A. Ochroleuca* in Isopropyl.

Conc	Shaking by Hand	Shaking by Sonic (10min)	Shaking by Sonic (20min)
75mg	Insoluble ppt	Insoluble ppt	Small Insoluble Particles
50mg	Insoluble ppt	Insoluble ppt	Small Insoluble Particles

Evaluation of Base

The result of comparison of the cream base suggests that all of them were similar in quality and stability. However. pH and texture of the cream base were different. B1, B2, B3 were found to be out of range 5.6 to 6.8 which is good for skin pH due to adding addition of triethanolamine which increases the pH. The base B4 was the best, it was more attractive and found to be in the range of skin pH due to excluding the triethanolamine, also it shows good spreadable property than the other. Moreover, B1 was stiffer due to including high amount of cetomacrogol and beeswax, while B2, B3, B4 were smooth due to decreasing the amount of cetomacrogol and beeswax.

Evaluation of Cream Formulations

From above results, the B4 base was selected for the preparation of herbal cream. The two different creams namely F1 and F2 comprising of different concentration of the extracts 1% and 2% respectively. All of the formulated creams were evaluated PH, viscosity, removability, irritability, color and spreadability as shown in Table 5. In this study, *Argemone ochroluca* cream was successfully formulated, packaged in Aluminum tubes of 20g net weight, and labelled. The backbone of the formula used o/w base. The pH of cream was found to be in range 6.19-6.21 which is good for skin pH. The formulation properties of the cram, on visual observation were a homogeneous pale-yellow colored semisolid with pleasant odor. The viscosity of cream was 15,040 and 21,560 cps which indicates that the formulation has the desired viscosity required for semisolid formulation for proper packaging. The formulations were easily spreadable by applying small amount of shear. The cream applied on skin was easily removed by washing with tap water. Both formulations show no redness, edema, inflammation and irritation during studies. These formulations are safe to use for skin. The formulated cream exhibited the desired proprieties of consistency, spreadability, physicochemical stability and appearance may make it cosmetically acceptable. As shown in Table 5.

Table 5: Evaluation of *A. Ochroleuca* Cream Parameters at Room Temperature.

Parameters	Formulation	
	F1(1%)	**F2(2%)**
Color	Pale Yellow	Pale Yellow
Visual Appearance	Smooth and Consistent	Smooth and Consistent
Foreign Particle	Very Small Particle	Free from Particle
Odor	Pleasant Odor	Pleasant Odor
pH	6.21	6.19
Viscosity (cps)	15,040	21,560
Remove Ability	Easy	Easy
Irritability	No	No
Spreadability	Good	Good

CONCLUSION

Argemone ochroleuca is one species of papaveraceae family, it has antimicrobial agent for wound healing activity against many species of bacteria and candida. Different concentrations of *Argemone ochroleuca* extract were prepared to measure the antimicrobial agent against some bacteria. It can used as wound healing activity, The evaluation tests were physical tests including pH, Spreadability, homogeneity, colour, odour, the antimicrobial and wound healing activity. It was concluded that the best formulation selected F1 (1%) and F2 (2%) were safe in respect to skin irritation and allergic sensitization and exhibited the desired proprieties of consistency, spreadability, physicochemical stability and appearance may make it cosmetically acceptable.

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