INTRODUCTION
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Herbal therapy has been one of the main branches of medicine for centuries in all parts of the world. The earliest mention of the plants is to be found in the Rigveda, which is one of the oldest repositories of human knowledge, having been written between 4500 and 1600 B.C. In this work, mention has been made of the soma plant and its effect on mankind. In the Atharvaveda, which is a later production, the use of drug is more varied, although it takes the form, in many instances, of charms, amulets, etc. It is in the Ayurveda, which is considered as foundation stone of the ancient herbal medical science of India, that definite properties of drugs and their uses have been given in details (Chopra et al., 1958). The practice continues today because of its biomedical benefits and place in cultural beliefs in many parts of the world. The economic reality of the inaccessibility of modern medication for many societies has also played a major role in the broad role of herbal medicine. With advancement in science, it is been realized that the medicinal plants, which are potential resource for pharmaceutical products, requires to be proven safe and effective. Argemone is considered as one of the traditional folk remedies for cancer, catarrh, cholecystitis, cold, colic, dysuria, eruptions, fever, headache, herpes, inflammation, itch, parturition, pink eye, rheumatism, tooth ache and many more.

The plant reportedly destroys worms, cures itching, leprosy, leukoderma, inflammations, bilious fevers, useful in strangury, an antidote to various poisons. It enriches blood, is a good expectorant and aphrodisiac (Kirtikar and Basu, 1933) and is useful in colds and pneumonia (Oakes and Morris, 1958). Urinary infections can be treated with a decoction of whole plant of Argemone mexicana along with roots of Latania verschaffeltii and leaves and stem of Caesalpinia bonduc (Gurib-Fakim et al., 1996) or by using a tea made from boiling Argemone mexicana plant (Elridge, 1975). Whole plant including roots is boiled and consumed in thick consistency for curing hepatitis and taken as a tea to cleanse body, improve fluid balance and regulate urination (Halberstein and Saunders, 1978). A drink made by boiling Argemone mexicana with chips from Bursera simaruba is useful for high blood pressure (Asprey G.F. and Thornton, 1955). The plant is used as a purge in Costa Rica and as a cure for drunkenness in Guatemala. Curacao
natives take young leaf tea for asthma, cardosis, cough and fever. Bahamians use it for hepatitis, Jamaicans for cold and fever, Yucatanese for hepatosis, and jaundice. Venezuelans use it for cancer, epilepsy and malaria. The latex is widely used for ophthalmia, ringworms, scabies and warts. A variety of medicinal uses have been attributed to different parts of *Argemone mexicana*. However, it must be emphasized that none of the prior art teaches use of the leaves of *Argemone mexicana* systematically for treatment of psoriasis. Thus the use of the extract prepared from only the leaves of *Argemone mexicana* for the treatment of psoriasis and the method for treatment by oral administration of the extract is novel and inventive.

In spite of the fact that *Argemone mexicana* has been known and widely used, the literature that identifies various medicinal uses of this plant provides no information to support the asserted effectiveness of the plant. The active components of *Argemone mexicana* responsible for medicinal activities are also unknown, though the literature reports the presence of alkaloids, flavonoids, amino acids, organic acids and sugars in the plant. The skin disorders like psoriasis is characterized by inflammatory and abnormal epidermal keratinocytes hyper-proliferation resulting to hyperplasia, thickening of the epidermis and presence of red scale plaques. The chronic skin condition recognized for its peculiar clinical symptoms characterized by circumscribed red patches covered with white scales a resulting itchy flaky skin. Psoriasis is a very visible disease; it frequently affects the face, scalp, trunk and limbs. The lesions in this chronic disease typically are subjected to remissions and exacerbations. Although psoriasis manifests as a skin disorder, it is believed to be a disease of impaired or defective cell mediated immunity. These days, psoriasis is portrayed as an autoimmune disease, where activated T-lymphocytes, producing multiple cytokines, cause secondary epithelial abnormalities. Dysregulated lymphocytes produced cytokines that stimulate the proliferation of apoptosis-resistant keratinocytes. Psoriatic skin lesions are characterized by inflammation, with T cells and neutrophils infiltrating both the dermis and epidermis and excessive scaling related to epidermal hyperproliferation and aberrant keratinocyte differentiation (Reich et. al. 2001). The defect in psoriasis appears to be overly rapid growth of keratinocytes and shedding of scales from the skin surface. Drug therapy is directed at slowing down
this process. The symptoms observed in psoriatic patients include hyperplasia and abnormal cornification of epidermal cells ascribed to the excess turnover of the cells by hyper metabolism, asthenia of inflammatory response in the epidermal layer, vasodilatation and leukocyte migration and infiltration into the epidermal cell layers (Beutner, 1982). However, it is now recognized that epidermal hyperplasia is a reaction to the activation of immune system in focal skin regions, which, in turn, is mediated by CD8+ and CD4+ T lymphocytes that accumulate in diseased skin. Indeed, psoriasis is now recognized as the most prevalent T cell-mediated inflammatory disease of humans. Because of clinical appearance of psoriasis is largely caused by epidermal changes, the disease has traditionally been considered one of excessive keratinocyte proliferation and abnormal differentiation. Within psoriatic lesions, the keratinocyte cell cycle time is reduced approximately 8 fold (36 vs. 311 hours in normal skin) and the number of dividing cell is doubled, resulting in a hyperplastic epidermis. More recently, infiltration of T lymphocytes in skin lesions has been recognized to be an integral feature of psoriasis. Current evidence suggests that epidermal changes in psoriasis are caused by actions of T lymphocytes in skin lesions. 

Argemone mexicana has also been reported effective against various skin disorders including Psoriasis. However, mechanism of action for therapeutic values is yet to be explored with the pathophysiology of the disease studied so far. As there are not enough evidences produced by the common scientific approaches to answer question of safety and efficacy of these herbal medicines, therefore present study is planned to carryout safety evaluation and to study toxicity profile of this herbal remedy called Argemone mexicana (Mexican poppy).

Keeping in view the above clinical needs, present study is planned to characterize and establish toxicity, safety and pharmacokinetic profiling of Argemone mexicana with following objectives:

(1) To characterize and study the profile of Argemone mexicana.
(2) To obtain information concerning toxicity of Argemone mexicana, when administered in

(i) Wistar Rats
(ii) Swiss mice; as single/ Repeated doses by
    (a) Oral route
    (b) Intravenous Routes.
(3) To evaluate local irritant effect on rabbit skin, following a single application of the plant extract.

(4) To determine the degree of ocular irritation produced by the plant extract following a single instillation to rabbit eye.

(5) To assess geno-toxicity potential by studying *in-vitro* chromosomal aberration induction potential in human lymphocytes.

(6) To assess micronucleus induction potential in Swiss mice. The micronucleus test is a mammalian *in vivo* test, which detects damage to the chromosomes or the mitotic apparatus induced by test article/chemical.

(7) To evaluate the photo-toxicity potential in Swiss mice.

(8) To obtain the information regarding delayed dermal contact sensitizing (Hypersensitivity) potential after repeated exposure to Swiss mice and also to find out any adverse effect likely to occur due to dermal exposure of the extract of the plant.

(9) To determine pharmacokinetic parameters and dose proportionality/linearity in wistar rats.