International Journal of Science and Research (IJSR)
ISSN (Online): 2319-7064
Index Copernicus Value (2015): 78.96 | Impact Factor (2015): 6.391

Formulation and Evaluation of Herbal Gel Containing Methanolic Extract of *Annonasquamosa* Leaves

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Abstract: ***Herbal medicine has become an item of global importance both medicinal and economical. Although usage of these herbal medicines has increased, their quality, safety and efficacy are serious concerns in industrialized and developing countries. Herbal remedies are getting increasing patient compliance as they are devoid of typical side effects of allopathic medicines.The present research has been undertaken with the aim to formulate and evaluate the herbal gel containing Annonasquamosaleaf extract. The gel formulation was designed by using carbopol 934, Annonasquamosaleaf extract, polyethylene, sodium sulphite and required amount of distilled water. The skin ph (6.8-7) was maintained by drop wise addition of tri-ethanolamine. The physicochemical parameters of formulations such as ph, spreadability, viscosity and rheological studies, extrudability, drug content uniformity and drug polymer compatibility studies were determined. The results showed that the formulation containing Annonasquamosaextract shows the drug content release which is above average. The ph of all formulations was found to be compatible with the normal ph range and so the chances of skin irritation are least.***

Keywords: *Annonasquamosa* leaves extract,carbopol-934, herbal gel

1. Introduction

In modern times, the use of herbal products has significantly increased in the developed countries as well as in several other countries. According to a world health organization estimate, 80% of the world's population presently uses herbal medicine for some aspect of primary health care. Many of the species are used in traditional medicines for the treatmentof a variety of diseases.However among the estimated 2,50,000-4,00,000 plant species, only 6% have been studied for biological activity and about 15% have been investigated phytochemically. The therapeutic efficacy of many indigenous plants, for various diseases has been described by traditional herbal medicinal practitioners. There are several reasons that people use plants for medication. This includes improvement of health after herbal treatment, low cost of the drugs, non-availability of synthetic drugs particularly in the rural areas etc. Annonaceae is one of the biggest families, whichcomprising about 130 genera over 2000 species are *annona*, with 150 species, genera, the species of *Annonasquamosa*is a small evergreen tree reaching 6-8 meters (20-26 ft) tall,is commonly found in deciduous forests, cultivated throughout india and other countries. It is commonly called as custrardapple; it isnative of West Indies. The plant is traditionally used for the treatment of epilepsy, dysentery, cardiac problem, worm infection, constipation, hemorrhage, antibacterial infection, dysuria, fever, and ulcer. It also has antifertility, antitumor and abortifacient properties. Several activities has been studied on the plant of *Annonasquamosa*like antimutagenic, antidiabetic, licicidal, hepatoprotective, antithyroid, antigenotoxic, antiplasmodial, molluscicidal, analgisic activity and antimicrobial activity. However, suitable dosage formulation of antimicrobial activity of leaves for topical use is still not reported. With the importance of above literature survey, in our present investigation we here in report a suitable gel formulation having methanolic extract of *Annonasquamosa* leaves.

2. Material and Method

Plant material

The leaves of *Annonasquamosa* were collected in fresh bags from empress botanical garden, pune, maharashtra, india and brought to laboratory. The collected leaves were initially rinsed with distilled water to remove soil and other contaminantsand shade-dried on paper at room temperature.

Preparation of extracts

The leaves of *Annonasquamosa* were thoroughly cleaned with water to remove dust particles and shade-dried at room temperature and reduced to coarse powder using a mechanical mixer. The powderwas subjected to extraction by cold maceration using n-hexane, petroleum ether, ethanol, and methanol to obtain their respective extracts. To 5g of the powdered drug, 50 ml of each solvent was added and stirred occasionally.The mixture was filtered after 48 hours, and the solvent was evaporated at 40^{o}c using evaporator. The percentage yields of n-hexane, petroleum ether, ethanol and methanol extractswere found to be 0.75% w/w, 1.54% w/w, 2.24%w/w and 3.5% w/w, respectively, which are stored in refrigerator until further use.

Preparation of herbal gel

The required quantity of carbopol-934 was slowly sprinkled with continuous stirring into weighed amount of water to get a uniform dispersion and then kept overnight for hydration. The accurately weighed amounts of drug along with other additives were poured in the fixed amount of hydrated carbopol-934 dispersion with constant mechanical stirring. The composition of herbal gel prepared from methanolic extract of *Annonasquamosa*is tabulated in table 1.

Table 1: Composition of various gel formulations containing *Annonasquamosa E*xtract

Ingredients	F11	F12	F21	F22	F31	F32
Carbopol-934	1.5g	1.5g	1.0g	1.0g	0.75g	0.75g
Polyethylene	10g	10g	10g	10g	10g	10g
Triethanol amine	1.5g	1.5g	1.5g	1.5g	1.5g	1.5g
Sodium sulphite	0.1g	0.1g	0.1g	0.1g	0.1g	0.1g
Plant extract	1%	2%	1%	2%	1%	2%
Water up to (ml)	100	100	100	100	100	100

Evaluation of herbal gel

All the prepared gel formations were subjected for preliminary evaluations as follows:

A] ph

The ph of all the formulations was determined by using digital ph meter. 1.5gm of gel was accurately weighed and dispersed in 15ml of distilled water and stored for two hours. The measurement of ph of each formulation was carried out in triplicate and the average values are represented in table 2. The ph of dispersions was measured using ph meter.

Table 2: ph values of gel formulations of *Annonasquamosa*

Sr. No.	Formulations	Ph value
1	F11	7.3
2	F12	7.4
3	F21	7.1
4	F22	7.0
5	F31	6.8
6	F32	6.9

B] Viscosity and rheological studies

Brookfield viscometer was used to determine the viscosities of gels. Rheological characteristics were tested at 25^{o}c using brookfield viscometer (lvdv-ii+p). The measurement was made over the whole range of speed settings from 10rpm to 100rpm with 30 seconds between two successive speeds and then in a descending orders.

Table 3: Viscosity of gel formulation of *Annonasquamosa*

Sr. No.	Formulation	Viscosity (cps)
1	F11	1987
2	F12	1996
3	F21	1788
4	F22	1803
5	F31	1612
6	F32	1624

C] Spreadability

Spreadabilty can be expressed as the extent of area to which the gel readily spreads on application to skin or affects part. Spreadability is calculated by using the formula:

$$S = ml/t$$

Where, m = weight tied to upper slide, l = length moved on glass slide and t = time taken to separate the slides completely from each other. Spreadability of different formulation was recorded as below:

Table 4: Spreadabilty of formulation at the time of preparation

Formulation	T1	T2	T3	Mean time	Spreadability
F11	6.4	6.5	6.4	6.5	24.90
F12	6.8	6.7	6.6	6.7	24.51
F21	5.4	5.7	5.7	5.6	29.60
F22	5.8	5.6	5.7	5.7	29.12
F31	5.0	5.1	4.9	5.0	33.20
F32	5.2	5.1	5.2	5.2	31.90

D] Drug content uniformity

1 gm of gel was accurately weighed and transferred to 100ml volumetric flask to which about 70ml of methanol was added and stirred followed by making up volume to 100ml with methanol. The content was filtered using filter paper. A quantity of 1 ml was pipette out from the filtrate and suitably diluted with methanol. Then the extract was estimated using jasco v630 spectrophotometer at respective $\lambda_{max.}$

Table 5: Drug content study of prepared topical gel formulation

Sr. No	Formulation	% drug content
1	F11	55.66
2	F12	57.4
3	F21	78.4
4	F22	78.8
5	F31	91.8
6	F32	92.2

E] Extrudability

Extrudability can be expressed as the force required to exude material out of the tube; determining the consistency of preparation.

The extrudability was calculated using the following formula:

Extrudability = applied weigh to extrude gel from tube (gm) / area (cm^2).

Table 6: Extrudability of formulations

Formulation	Net wt. of formulation in tube (g)	Wt. Of gel extruded (g)	Extrudability amount (%)	Grade
F11	2	1.48	74.0	++
F12	2	1.44	72.0	++
F21	2	1.59	79.5	++
F22	2	1.56	78.0	++
F31	2	1.71	85.5	++++
F32	2	1.69	84.5	++++

3. Conclusion

This research work was carried out to develop a new topical herbal gel formulation for topical application. The prepared herbal gel was further evaluated for ph, viscosity, extrudability, spreadability and drug content uniformity.The optimized formulation f32 complies with all the parameters.

4. Results and Discussion

The various physicochemical properties of the prepared gel formulations are shown above. From the result it is clear that all the gel formulation shows good gelling property and

homogeneity. The ph of all formulations was in the range compatible with normal ph range of the skin. The drug content released was also above average. The rheological behaviors of the gel formulations were also studied with brookfield viscometer. The results indicated the viscosity of gel formulations was consistent neither too thick nor too thin. A comparative study of viscosity and spreadability showed that with the increase in the viscosity of formulation, the spreadability decreased and vice versa. The ft-ir spectra of the gel formulations did not show the presence of any additional peaks of the drug remained unchanged in the mixture were observed in ft-ir spectra. Thus overall the gel formulation f32 has all the desirable properties that must be present in an ideal gel formulation.

5. Future Prospects

Annonasquamosa leaves have anti-microbial properties and the extract of leaves of this plant cannot be applied directly on skin, so a suitable formulation is required to for application. As the formulation f32 complies with all the parameters of an idea gel, it can be compete with any herbal marketed formulation. In-vivo studies and in-vitro studies areneeded to be carried out using suitable model to make it suitable for application on human skin.

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