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Formulation and evaluation of an herbal mouth gel containing methanolic extract of *Psidium guajava* tender twigs for treating oral mucositis

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ABSTRACT

P. guvajava is used in many parts of the world as a for treating number of diseases and disorders like diabetes, microbial infections, Hepato toxicity, diarrheal, algesia & inflammation. It is also used for Treating mutagenicity, cancer, infantile rotaviral enteritis this guvajava possesses Inotropic effect, Spasmolytic effect, Immuno modulator activity so it can be used for the Treatment of acne, anti-proliferative activity, Anti-pyretic, Contractile effect, Hypotensive & Malaria. In India it is used for Spermatoprotective activity. To hence the properties the present study was chosen to formulate a herbal gel for treating oral mucositis. In the present study methanolic extract of leaves of *P.guvajava* was formulated as a gel and investigated for its physicochemical as well as for its mucosal irritation activity. Methanolic extract of dried leaves of *P.guvajava* were subjected to preliminary formulation studies. Different gel formulations of Methanolic extract of dried leaves of *P.guvajava* (1%, 2% & 3% w/v) were prepared using polymer carbopol 940 by varying their concentrations. These formulations were evaluated for the following parameters: physical evaluations like pH, colour, odour, greasyness, consistency, Homogeneity, and mucosal irritation. Stability studies were also performed to this formulation on 0 day, 15th day & 30th day as above. By the results, it was clear that the *P.guvajava* herbal mouth gels were safe, stable and good for treating the oral mucositis. So further we are planning to conform the activity of *P.guvajava* herbal mouth gel to treat oral mucositis on laboratory animals.

INTRODUCTION

Throughout the world, the interest in the study of medicinal plants as a source of medicinal compounds has increased. In developing countries like India, it is recognized that plants are the main medicinal source to treat number of infectious diseases¹. The World Health Organization has estimated that 80% of the earth and 6 million inhabitants rely only upon traditional medicines for their primary health care needs. Major part of the treatment involves the use of plant extracts or their active principles. The effective use of herbal medicine was proved by number of scientists in many parts of the world have proven to humanity by carrying out an extensive research work². India has rich tradition of plant-based knowledge of healthcare. The use of the plant-based medication is gradually becoming popular

throughout the world³. Approximately, half of the world's twenty-five best selling pharmaceutical agents are derived from natural products⁴. A gel is colloid that is typically 99% wt liquid, which is immobilized by surface tension between it and a macromolecular network of fibers built from a small amount of a gelatin substance present. Topical drug administration is a localized drug delivery system anywhere in the body through ophthalmic, oral, rectal, vaginal and skin as topical routes⁵. Topical application of gels at pathological sites offer great advantage in a faster release of drug directly to site of action, independent of water solubility of the drug as compared to creams and ointments^{6,7}. The leaves, tender twigs and bark of *P. guajava* tree have an ancient history of medicinal uses that are still used today for the treatment of number of diseases. Guava is a large tropical evergreen shrub or small shade tree⁸. The *Psidium guavajava* leaves of the plant have been mixed up in management of stomachache, diarrhoea, wounds, ulcer and toothache and in the diabetes⁹. The infusion and decoction of *Psidium guajava* leaves are used in the leucorrhoea state¹⁰. In the Latin America, Central and West Africa and South East Asia the *Psidium guavajava* plant leafs decoction are

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used as swelling of the mouth, gargles or the sore throats, laryngitis, external ulcer on the skin and vaginal irritations^{11,12}. The *Psidium guajava* leaves contain the anti-inflammatory property and is used in various lung problems. The aim of the present study is to establish the Formulation and Evaluation of a Herbal mouth gel containing methanolic extract of *Psidium guajava* L. tender twigs for treating oral mucositis with a view to provide a scientific basis for their traditional use.

MATERIALS AND METHODS

Collection of Plant Materials

The tender twigs (younger leaves) of *Psidium guajava* were collected from the Guava nurseries of Sathupally and Aswaraopeta region of Telangana, India in January 2016, the collected leaves were shade dried for 7 days then powdered by mechanical manner and packed in to an air tight container. The fresh plant materials and powdered leaves were sent for the authentication to Andhra University. The samples were identified and authenticated by Dr.Padala, Dept. of Botany, south campus, Andhra University, Vishakapatanam, Andhra-pradesh, India. Specimen of the collected plant sample was deposited in the Department of Pharmacology, Mother Teresa pharmacy college, Sathupally, Khammam dist, Telangana, India for future reference.

Chemicals required for the extraction and formulation of gel

Methanol, Carbapol940, Methyl paraben, Propyl paraben, Poly ethylene glycol, Glycerine, Methanol and Sodium saccharin are the chemicals used in this study were purchased from Chaithanya Scientifics, Vijayawada, Andhra Pradesh.

Extraction Procedure

Maceration method was used for extraction. Weigh accurately 292.5 g of powdered leaves and the powdered leaves were soaked for 24 h in 1 L of methanol and placed on a magnetic stirrer. After 24 h, the mixture was then filtered (drain) to collect the methanolic solution. The solution was subjected to distillation for recovering the solvent then the remaining concentrated liquid was poured into evaporating dishes and was placed on a water bath to hasten the rate of evaporation at about 45-50°C. The obtained dried product was collected and preserved in air tight containers for the further formulation work¹³.

Method of Preparation of Gel Formulation¹⁴

Different proportions of carbopol 940 and Sodium CMC were dispersed in distilled water or deionized water with continuous stirring with the help of mechanical stirrer. In another beaker weigh and transfer the required quantity of extracted drug powder and dissolved in polyethylene glycol and it was dissolved by using sonication for 15mints. Dissolve the required quantity of preservatives & Sodium saccharine in sufficient quantity of distilled water and after that, it was mixed to the first one. Finally, the prepared solution was added to Carbopol 940 gel with continuous stirring to obtain the gel in required consistency. During the

trial, the concentrations of carbopol and sodium CMC were increased and decreased to overcome several problems like homogeneity, spreadability and viscosity. By using this method we prepare three different formulations with guava leaves extract with three different concentrations like 1%, 2% and 3% respectively.

Table 1: Master formular for 100 g

| Ingredients | Quantity in gm or ml |
|---------------------------------------|----------------------|
| 1. <i>Psidium guajava</i> drug powder | 1 |
| 2.Carbapol | 30 |
| 3.Methyl paraben | 1 |
| 4.propyl paraben | 1 |
| 5.Poly ethylene glycol | 10 |
| 6.glycerine | 5 |
| 7. Sodium saccharin | 5 |
| 8. Distilled water | q.s |

Table 2: Formula for 30 g for 1% gel preparation

| Ingredients | Quantity in gm or ml |
|---------------------------------------|----------------------|
| 1. <i>Psidium guajava</i> drug powder | 0.30 |
| 2.Carbapol | 9 |
| 3.Methyl paraben | 0.30 |
| 4.propyl paraben | 0.30 |
| 5.Poly ethylene glycol | 10 |
| 6.glycerine | 1.5 |
| 7. Sodium saccharin | 1.5 |
| 8. Distilled water | q.s |

Table 3: Formula for 30 g for 2% gel preparation

| Ingredients | Quantity in gm or ml |
|---------------------------------------|----------------------|
| 1. <i>Psidium guajava</i> drug powder | 0.60 |
| 2.Carbapol | 9 |
| 3.Methyl paraben | 0.30 |
| 4.propyl paraben | 0.30 |
| 5.Poly ethylene glycol | 10 |
| 6.glycerine | 1.5 |
| 7. Sodium saccharin | 1.5 |
| 8. Distilled water | q.s |

Table 4: Formula for 30 g for 3% gel preparation

| Ingredients | Quantity in gm or ml |
|---------------------------------------|----------------------|
| 1. <i>Psidium guajava</i> drug powder | 0.90 |
| 2.Carbapol | 9 |
| 3.Methyl paraben | 0.30 |
| 4.propyl paraben | 0.30 |
| 5.Poly ethylene glycol | 10 |
| 6.glycerine | 1.5 |
| 7. Sodium saccharin | 1.5 |
| 8. Distilled water | q.s |

Evaluation of gel¹⁶

The prepared gels were evaluated for appearance, pH, drug content, permeability studies and stability studies. All the gels were visually evaluated for presence of fibres and particles.

Table 5: Stability and evaluation studies of P.guvajava herbal mouth gel

| Parameters | Day-0 | | | Day-15 | | | Day-30 | | |
|------------------------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|
| | F ₁ | F ₂ | F ₃ | F ₁ | F ₂ | F ₃ | F ₁ | F ₂ | F ₃ |
| Physical parameters | | | | | | | | | |
| Color | Green | Green | Green | Green | Green | Green | Green | Green | Green |
| Consistency | Good | Good | Good | Good | Good | Good | Good | Good | Good |
| Greasiness | Non greasy | Non greasy | Non greasy | Non greasy | Non greasy | Non greasy | Non greasy | Non greasy | Non greasy |
| Odour | sweetish | sweetish | sweetish | sweetish | sweetish | sweetish | sweetish | sweetish | sweetish |
| Homogeneity | +++ | +++ | +++ | +++ | +++ | +++ | +++ | +++ | +++ |
| pH | 6.8 | 6.8 | 6.8 | 6.8 | 6.8 | 6.8 | 6.8 | 6.8 | 6.8 |
| Effect on oral mucosa | Non-irritating | Non-irritating | Non-irritating | Non-irritating | Non-irritating | Non-irritating | Non-irritating | Non-irritating | Non-irritating |

Physical appearance

The physical appearance of the formulation was checked visually.

- **Color:** The color of the formulations was checked out against white background.
- **Consistency:** The consistency was checked by applying on skin.
- **Greasiness:** The greasiness was assessed by the application of the gel on to the skin.
- **Odor:** The odor of the gels was checked by mixing the gel in water and observing the smell.

Determination of pH

The pH of gel was determined using digital pH meter (ELICO LI 120) by dipping the glass electrode completely into the gel system.

Determination of viscosity

Viscosities of the formulated gels were determined using Brookfield Viscometer, spindle no. 7 and spindle speed 60 rpm at 25°C were used for gels, the corresponding dial reading on the viscometer was noted

Determination of Homogeneity

All the developed gels were tested for homogeneity by visual inspection after the gels have been set in the container. They were tested for their appearance and presence of any aggregates.

Mucosal irritation study on Animal:

The primary skin irritation test was performed on albino rats weighing about 150-200g. The animals were maintained on standard animal feed and had free access to water *ad libitum*. The animals were kept under standard laboratory condition. Overnight fasted animals are selected and divided in to 4 groups each group contains 6 animals; these overnight fasted animals were given free access to drinking water. To these 4 groups of animals 1%, 2%, 3% herbal mouth gel & gel base was applied respectively by using a ear bud on to the inner mucosal layers of mouth cavity and under the lips. Then keep the animals group wise in the separate cages for cage side observations.

RESULTS AND DISCUSSION

The preliminary step involved was the extraction of leaves of *P.guvajava* with methanol using Maceration process. 1023.75 grams of dried powdered leaves was taken and extracted with 3500 ml of methanol batch wise (146.25g/500ml) and the extractions are subjected to distillation for recovering the solvent. Finally the remaining crude extract was subjected to drying by pouring in the petridish then the dried powdered extract was collected and weighed for calculating the final yield. The percentage yield of *P.guvajava* leaf extract was found to be 5.49%.

$$\text{The percentage yield of crude extract} = \frac{\text{Weight of the extract}}{\text{Weight of dried leaves powder}} \times 100$$

The percentage yield of crude extract is 5.49%.

Three different formulations of herbal gel was prepared using carbopol polymer and were evaluated. In the past, it was the practice in many pharmaceutical manufacturing companies to evaluate the stability of pharmaceutical preparations by observing them for a year or more, corresponding to the normal time that they would remain in stock and in use. Such approach was time consuming. Now a day's Accelerated stability studies are used by most of the pharmaceuticals for stability evaluation of all types of formulations¹⁷. Though the primary aim of this work was to develop a herbal mouth gel but the stability study will mark an important advancement in the area of phytopharmaceuticals. The prepared herbal mouth gel was evaluated immediately after preparation and in two different time intervals i.e 0 day, 15th day and 30th day and all the tested parameters like physical evaluations like pH, colour, odour, greasiness, consistency, Homogeneity, were determined and The mucosal irritational study was also conducted and the results were tabulated below.

The final herbal gel found to have a pH: 6.8, the values of surface pH were within the range of natural pH this indicates that the formulation can be used without any irritation in the oral cavity. The results of stability study of the herbal gel reveal that no changes were noticed in the physical and biological parameters like pH, colour, odour, greasiness, consistency, Homogeneity, were determined and The mucosal irritation which was stored at room temperature. By the above results it was clear that

the herbal mouth gels were safe, stable and good for treating the oral mucositis. So further we are planning to conform the activity of *P.guajava* herbal mouth gel to treat oral mucositis on laboratory animals.

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