

Journal of Current Pharma Research

(An Official Publication of Human Journals)

An International Peer Reviewed Journal For Pharmacy, Medical & Biological Science DOI: 10.25166 CODEN: JCPRD6 NLM ID: 101744065



Human Journals **Research Article** May 2023 Vol.:17, Issue:4 © All rights are reserved by Pratiksha Jadhav et al.

Formulation and Evaluation of *Azadirachta indica, Psidium guajava and Curcuma longa* Polyherbal Gel for Mouth Ulcer

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Pratiksha Jadhav^{*1}, Amruta A.Nangare², Ashish A. Jagtap², Atul R.Chopade³, Hemant S. Kandle³, Vaishnavi P. Somade⁴

¹Yashwantrao Chavan College of Science, Karad 415124 Maharashtra, India.

²Dept of Quality Assurance, Rajarambapu College of Pharmacy, Kasegaon, Sangli, 415404 Maharashtra, India.

³Rajarambapu College of Pharmacy, Kasegaon, Sangli, 415404 Maharashtra, India.

⁴Krishna Institute of Pharmacy, Karad 415124, India.

 Submitted:
 05 May 2023

 Accepted:
 20 May 2023

 Published:
 25 May 2023



www.jcpr.humanjournals.com

Keywords: Herbal gel, Mouth ulcer, *Azadirachta indica L.*, *Psidium guajava L.* and *Curcuma longa Linn*.

ABSTRACT

The aim of present study is to formulate and evaluate polyherbal oral gel containing the extracts of powdered Azadirachta indica Linn leaves, Psidium guajava Linn leaves And Curcuma longa Linn rhizomes. Natural medicines are preferred in the belief that they are safe and have less side effects. The polyherbal oral gel was prepared by using guava leaf extract, neem leaf extract, turmeric rhizome extract, carbopol 940, propylene glycol 400, methyl paraben, propylparaben, Triethanolamine, glycerin and required quantity of water. Neem leaves and its constituents. The prepared gel formulation was evaluated for its various properties such as Colour, Odour, Consistency pH, homogeneity, Viscosity, Spreadability, Extrudability, Clarity, Gel strength etc. The formulated herbal gel showed that the all the physicochemical parameters were found to be compatible with the normal range. Developed herbal oral formulation is used for curing mouth ulcer. The gel formulation was safe, stable and effective.^[1]

INTRODUCTION:

Topical preparations such as gels, ointments, lotions and creams are the important drug delivery systems because it is convenient in delivering drug to a localized area of the skin. Gel is semi-solid topical preparations which provides rapid onset of action, long-term efficacy and high patient satisfaction.^[1] Gels are mainly semisolid preparations having a liquid phase that has been thickened with some other components. Gel preparations for topical applications or to certain mucosal surfaces for local action or percutaneous penetration of medicament. Mouth ulcer is common disorder in which painful round or oval sores that form in the mouth, most often on the inside of the cheeks or lips appeared. Common causes of mouth ulcers include nutritional deficiencies like iron, vitamins mainly vitamin B12 and C, poor oral hygiene, infections, stress, indigestion, mechanical injury, food allergies, skin diseases.^[2] Over three fourth of world population depends mainly on the plants and plant derived herbal medicines. Herbal drugs constitute 25% of total drugs in developed countries such as United States, while in fast developing countries like China and India the contribute above 80%. Thus, the economic importance of medicinal plants in India is much more than other countries.^[3]

Neem, Turmeric and Guava are among the most common herbal products used in dentistry. Azadirachta indica L. also called as Neem is medicinal plant belongs to family Maliaceae. Neem contains steroids alkaloids, triterpenes, flavonoids and anthraquinone glycosides. It may be helpful for skin diseases such as acne, eczema, psoriasis and scabies. Neem is the most useful traditional medicine as a source of many herbal remedies in the Indian culture. The extracts of Neem have antiviral, antibacterial, antifungal, anthelmintic, antiallergic, antidermatic, wound healing and anti- inflammatory properties.^[4] Guava (*Psidium guajavaL.*) leaves have been used to treat several disorders such as rheumatism, diarrhea, diabetes mellitus, wound sore throat, cough and it also gives antibacterial activity, anticancer activity. The fruit of Guava constitutes vitamin A, C, iron, phosphorous, calcium and minerals. Ascorbic acid and citric acid are important ingredients of guava that plays important role in anti-mutagenic activity. Guava leaves has some components which play a role as fungistatic and bacteriostatic agents. The biological source of Turmeric is Curcuma longa L. which belongs to the family Zingiberaceae. Active constituents of turmeric are the flavonoid curcumin and various volatile oils including tumerone, atlantone and zingiberone. Volatile oil of Curcuma longa L. possesses anti-inflammatory and anti-arthritis activities. Water and fat

soluble extracts of curcumin exhibited strong antioxidant activity. In dentistry, turmeric plays a role in treating gingival and periodontal disease because of its astringent properties.



Fig. 1: Powdered extracts of Neem, Turmeric and Guava

MATERIAL AND METHODS:

The powdered extracts of Guava (*Psidium guajava* L.), Neem (*Azadirachta indica* L.) and Turmeric (*Curcuma longa* L.) were purchased.

CHEMICALS:

Carbopol 940, Methyl Paraben, Propyl Paraben, Propylene Glycol 400, Triethanolamine, Glycerine, Distilled Water.



EQUIPMENTS:

Digital balance, pH meter, Magnetic stirrer, Water bath, Ostwald's viscometer, Glass slides, Collapsible tubes.

Preparation of herbal gel:

15 ml of distilled water was taken in beaker and Carbopol 940 was dispersed in it with continuous stirring. Beaker was kept aside for half an hour to swell. In another beaker 5 ml of distilled water was taken and methyl paraben and propyl paraben were added by heating on water bath. The solution was cooled and then propylene glycol 400 was added in it. The powdered extract of neem, guava and turmeric was added to above mixture. The above solution was mixed properly with the solution having Carbopol940 with continuous stirring. Glycerine was added to it. Finally, volume was made up to 30 ml by using distilled water. For

adjustment required mouth skin pH (6.8-7) and obtain in gel consistency Triethanolamine was added drop wise.^[2]

Ingredients	Formula1	Formula2
Guava leaf extract	0.5gm	0.5gm
Neem leaf extract	-	0.5gm
Turmeric leaf extract	0.5gm	0.5gm
Carbopol 940	0.3gm	0.3gm
Methyl paraben	0.06gm	0.06gm
Propyl paraben	0.03gm	0.03gm
Propyleneglycol400	1.5ml	1.5ml
Triethanolamine	0.36 ml	0.36ml
Glycerine	0.45 ml	0.45ml
Distilled water	Upto 30ml	Upto 30ml

Table1: Composition of gel formulation



Fig 2: Prepared Polyherbal Gel

EVALUATION PARAMETERS

Physical Evaluation:

Physical parameters such as color, odour and consistency were checked visually.

Color: The color of formulation was checked by visual inspection.

Consistency: The consistency of formulation was checked by applying to the skin.

Odour: The odour of formulation was checked by mixing the gel in water and observing the smell. **Table2**.^[5]

Measurement of pH:

The pH of prepared gel was determined by digital pH meter. Dissolve 1 gm gel in 10ml distilled water and kept apart for two hours. Then pH of formulations was measured by dipping the glass electrode completely into the gel solution three times and the mean values were recorded in **Table3**.^[5]

Spreadability:

Spreadability is the time in seconds taken by two slides to slip off from the gel placed in between the slides under the direction of certain load. If the time taken for separation of two slides is less, t h e n the spreadability is better. Spreadability was calculated by formula;

S=M× L/T

Where, M=Mass tied to upper slide

L= length of glass slides

T = time taken to separate the slides spreadability of gel formulations Table 7.^[6]

Extrudability:

The standard capped collapsible aluminium tubes was used to fill the formulated gel and was sealed by crimping to the end. The weight of filled tubes was recorded and the tubes were sandwiched between two glass slides and were clamped. The weight of 500 gm was placed over the slides and the cap was removed to extrude. The amount of extruded gel was collected and weighed. Extrudability was determined by calculating the percentage of extruded gel.

When the extrudability is greater than 90% it is considered to be excellent.

When the extrudability is greater than80% it is considered to be good.

When the extrudability is70% then it is considered to be fair.

Extrudability of gel formulations were reported in Table8.^[7]

Viscosity:

The viscosity of the formulated gel was determined by Ostwald's Viscometer. The viscometer was mounted vertical position on a suitable stand. Water was filled into the viscometer upto markA. The time was counted for water to flow from mark A to mark B. The same procedure was repeated for the test liquid by using the above formula viscosity of the test liquid could be determined. Viscosity of gel formulation was reported in **Table6**.^[8]

Gel strength:

Gel strength is expressed in the terms of the time in seconds required by the weight to penetrate in the gel. The weight of 3.5 gm was placed on the surface of 5 gm of formulated gel. Gel strength was determined by reporting the time in seconds required by the weight to penetrate 0.5 cm in the gel ^[10]. The gel strength was then reported in **Table9**.^[9]

Anti-Fungal Activity:

The anti-fungal activity test was performed by using Candida albicans. Prepared nutrient brought and poured in to sterile petri plates and kept aside for drying and cooling. After that Candida albicans culture were spread by micron wireloop. A sterile cork borer measuring 6mm in diameter was used to drill holes 4 mm deep. Then place 0.5 gm of gel from each formulation in to these holes. Plates were then incubated at 27°C for 48 hr. The zone of inhibition (diameter in mm) was measured. Antifungal studies were reported in **Table 10.**^[10,11]

Clarity:

All the batches were visually inspected for clarity.^[12]

Homogeneity:

All the gel formulations were observed for homogeneity by visual inspection after the gels had been set into the container. They were tested for the presence and appearance of any aggregates reported in **Table5**.^[12]

Stability study:

Stability studies were performed to observe the effect of environmental conditions or storage conditions on formulation. The optimized formulation was studied for accelerated stability at 25° C temperature $60 \pm 5\%$ relative humidity, 30° C temperature $65 \pm 5\%$ relative humidity and 40° C temperature $75 \pm 5\%$ for 3 months as per ICH guidelines. The placed sample was withdrawn after 3 months interval and evaluated for physical appearance, pH, viscosity, spreadability, extrudability and gelling strength.^[13]

RESULT AND DISCUSSION:

• *Physical evaluation:*

Table2

Formulations	Color	Consistency	Odour
F1	Yellowish green	Good	Characteristic
F2	Yellowish green	Good	Characteristic

• Percentage yield:

Table3

Formulations	Percentage yield (%)
F1	92.88
F2	95.56

• *pH*:

Table 4

Formulations	рН
F1	6.9
F2	7.0

• Homogeneity

Table 5

Formulations	Homogeneity	٦
F1	Good	
F2	Good	

• Viscosity

Table 6

Formulations	Viscosity(cps)
F1	4600
F2	4800

• Spreadability:

Table no. 7

Formulations	Spreadability(gm.cm/sec)
F1	23.88
F2	26.87

• Extrudability:

Table 8

Batch	Weight of	Weight of gm	Extrudability
	Formulation	extruded	amount
F1	16.5	14.20	86.06%
F2	17.12	15.23	88.96%

Gelling Strength:

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Table 9

Formulations	Gelling strength
F1	40±0.15
F2	39±0.15

• Anti-fungal activity:

Table 10

Formulations	Zone of inhibition(mm)
Standard drug	25
F(mixed)	22
Blank	12

DISCUSSION:

From the above results, the prepared gel was yellowish green in color and had good homogeneity and gelling property. The pH of gel formulations was compatible with normal pH range of oral cavity. The rheological behaviour of gel formulation was studied with Ostwald's viscometer which indicated that the viscosity of gel formulation was neither too thick nor too thin. Spreadability study shows that with increasing the viscosity of formulation spreadability decrease and vice-versa. The gelling strength and extrudability is found in the suitable range. The gel formulation F (mixed) complies with all parameters of an ideal gel. Accelerated stability studies indicated that the physical appearance, rheological properties, extrudability, spreadability in the optimized formulation remain unchanged upon storage for 3 months. F(mixed) formulation showed good anti-inflammatory and antifungal activity against Candida albicans was checked which the main microorganism responsible for mouth ulcer.

CONCLUSION:

Herbal formulations are popular in the market because of its cost-effectiveness and absence of side effects. From the above experimental data clear gel with herbal ingredients like turmeric, guava, neem having good gelling strength and good rheological properties is formulated. It also has good antimicrobial activity and used in the treatment of mouth ulcers.

Acknowledgments: Our thanks to pharmacist and other students who took part in study.

Conflict of interest: None.

Financial support: Not applicable.

Ethics statement: None.

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Citation: Pratiksha Jadhav et al. Jcpr.Human, 2023; Vol. 17 (4): 44-53.

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