FORMULATION AND EVALUATION OF *PSIDIUM GUAJAVA* AND *CURCUMA LONGA* EXTRACTS BASED CHEWING GUM FOR TREATING MOUTH ULCER

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Abstract

The present invention provides a chewing gum for treating mouth ulcer. The chewing gum comprising of Psidium guajava extract; and Curcuma longa Linn extract; and pharmaceutically acceptable excipients. The chewing gum wherein the plant part used for the preparation of extracts are Psidium guajava leaf and Curcuma longa Linn rhizomes; wherein the chewing gum is used to treat oral diseases. The chewing gum for treating mouth ulcer, wherein the chewing gum is 10 used orally for the treatment. The chewing gum, wherein the amount of Guava leaves extracts and Curcuma longa Linn extract 50 mg to 150 mg.; Beeswax 80 mg; Glycerol 10 mg; Dextrose 24 mg; Calcium carbonate 24 mg; Polyvinyl pyrrolidine 210 mg; Magnesium stearate 4 mg; and Peppermint oil 3 mg. The developed chewing gums of Guava leaves extract was soft, Green in colour. The presence of glycerin at optimized concentration provided the softness for the developed chewing gum. The average drug content in the developed chewing gum was found to be 90.12%, which confirmed the success of the formulation and the methodology employed for its development. The drug stability for chewing gums may significantly affected by the chewing frequency, hence the percentage drug of the developed Chewing Gum was measured the maximum drug of 85.5%was reported after 45 days of study of batch F3.

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Keyword : Psidium guajava extract, Curcuma longa Linn, chewing gum, Polyvinyl pyrrolidine, mouth ulcer.

Introduction :

In developing countries like India, it is re ognized that plants are the main medicinal source to treat number of infectious diseases.[1]

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.[2] Diagnosis of oral ulcers at times may be challenging and therefore it is important to consider the differential diagnosis. History taking should include duration, associated symptoms, pattern of occurrence or recurrence and associated systemic conditions.[3]

Guava (Psidium guajava) is a tropical fruit and guava leaves are often used as a traditional medicine to treat wounds, diarrhea, cough, mouth sores, and dengue fever.

The guava leaf extract is reported to have antioxidant, anti-reaction nonenzimatik reducing sugar in patients with hyperglycemia, anti-inflammatory, and anticoagulants activities. Some studies show that guava leaves extract contains phenolic compounds such as Ferulic acid, Gallic acid and flavonoids such as catechins, quercetin, and kaempferol. [7] Moreover, the biological activity has been attributed to the bioactive composition of the leaves, to some specific phytochemical subclasses, or even to individual compounds. Phenolic compounds in guava leaves have been credited with regulating blood-glucose levels.[8]

It is widely distributed throughout India. The leaves and bark of P. guajava tree have long history of medicinal uses, that is still employed today.[9] The guava leaf has gone through phytochemical analysis and found to have alkaloids, carotenoids anthocyanins, vitamin-C, and triterpene.[10]

Turmeric in a present of Cur cumin is an orange yellow crystalline powder obtained from rhizome of Curcuma longa. Turmeric and cur cumin are believed to have anti-inflammatory, antioxidant, and even anticancer properties. Molecular Constituents Turmeric has numerous molecular constituents, each possessing a variety of biological activities. For instance, there are a minimum of 20 molecules that are antibiotic and 14 of its constituents have known cancer preventive activity.Also,12 of its molecules are antitumor, and the other 12 molecules have anti-inflammatory effects. It contains at least 10 molecular constituents with antioxidant properties, too. Overall, 326 biological activities of turmeric are identified. Three of the constituents that are widely researched in turmeric are gold-colored alkaloids curcuminoids, namely, cur cumin, bisdemethoxycurcumin, and demethoxycurcumin. [11]

Materials and Methods

Collection of plant material:

The fresh plant material of guava leaves were collected and fresh plant leaves were washed in distilled water and remove dust particle and shade drying was carried out in room temperature. *Curcuma longa Linn* was collected from local market. [12]

Preparation of plant extract:

The dried plant parts were reduced to coarse powder with a mechanical grinder. The powder was then subjected to extraction by soxhlet apparatus using ethenolic extract.

200g of dried guava leaves powder and 200 gm of *Curcuma longa Linn* rhizomes were extracted in 250ml of ethanol in soxhlet apparatus.

In this method, crude drug is placed in a thimble using of cotton plug. It is placed in chamber of the soxhlet apparatus.

The extracting solvent in flask is heated, and its vapors condensed in condenser. The condensed extractant drips into the thimble containing the crude drug, and extracts it by contact. When the level of liquid in chamber rises to the top of the siphon tube, the liquid contents of chamber siphon into flask. This process is continuous and is carried out until a drop of solvent from the siphon tube does not leave residue when evaporated.

After this process the extract is found but there is ethanol and water solvent present in it which has to be removed by different process.

The main advantage of this method is that large amounts of drug can be extracted with a much smaller quantity of solvent. This affects tremendous economy in terms of time, energy and consequently financial inputs.

At small scale, it is employed as a batch process only, but it becomes much more economical and viable when converted into a continuous extraction procedure on medium or large scale.

First of all, ethanol will be removed using Soxhlet apparatus. And keep the thimble empty in the soxhlet apparatus, no drug will be present in it.Then the extract is poured in a Petridis and water is evaporated in room temperature. [12-13]

Formulation of chewing gum

Chewing gum is mixture of natural or synthetic gums and resins sweetened with glycerin, artificial sweeteners and may also contain coloring agent.

Preparation of chewing gum:

Weight quantity of calcium carbonate and polyvinyl pyrrolidine were mixed in separate pestle mortar. Weighed quantity of bees wax and glycerol was taken

S.No.	Ingredients	F1	F2	F3
1	*Psidium Guajava* leaves extract and *Curcuma Longa* rhizomes Extract (1:1 ratio)	50 mg	100 mg	150 mg
2	Beeswax	80 mg	80 mg	80 mg
3	Glycerol	10 mg	10 mg	10 mg
4	Dextrose	24 mg	24 mg	24 mg
5	Calcium carbonate	24 mg	24 mg	24 mg
6	Polyvinyl pyrolidine	210 mg	210 mg	210 mg
7	Magnesium stearate	4 mg	4 mg	4 mg
8	Peppermint oil	3 mg	3 mg	3 Mg

Table 1: Formulation of chewing gum

and melted. Then weighed quantity of guava leaves extract was mixed in above mixture.

 taken and melted. Then weighed quantity of guava leaves extract was mixed in above mixture. The melted bees wax is poured into the mortar pestle. In which plasticizers are already present. Then all the remaining ingredients dextrose, magnesium stearate, peppermint oil were added and mixed well. The mixed chewing gum are poured in clean tray and give the proper shape of the chewing gum.[14]

Evaluation of Formulation [14-15]

Physical appearance

All prepared formulations were physically evaluated for parameters such as appearance, color, stickiness.

Fourier transformation infrared spectroscopy (FT-IR)

FT-IR spectrophotometer (Shimadzu-8400S, Japan) was used to study FT-IR spectra by KBr pellet method. FT-IR spectrum of Guava Leaves extract was compared with FT-IR spectra of formulations. Disappearance of peaks or shifting of peaks in any of the spectra was studied.

Weight variation:

Weight variation of all formulation was done by method described in experimental work. Weight of 10 chewing gums was taken in one batch and then average weight is calculated from that standard deviation is calculated

Thickness:

Chewing gum thickness is an important parameter to be controlled to facilitate packaging. Chewing gum thickness must be controlled within a ±5% variation of a standard value. Any variation within a particular lot should not be apparent to the unaided eye of the consumer. Thickness of all the formulations was measured using a Verniercalliper.

Uniformity of content:

The individual contents of active substance of 10 dosage units which were taken randomly were determined. The 10 dosage forms were crushed in mortar and extract equivalent to 10 mg of Guava leaves extract was taken. The extract was dissolved in 100 ml of methanol. The absorbance measurements of these solutions were taken

by UV–Visible spectrophotometer at 236 nm. The formulation complies with the test if the individual content is between 85% and 115% of the average content.

Stability studies:

Stability studies for developed CG an accelerated stability study for developed Chewing Gum was carried out as per ICH guidelines with necessary modifications. The Chewing Gum was exposed at different temperature conditions of 0.2°C, 30±2°C and 45±2°C for a period of 45 days. The Chewing Gum was tested for consistency, colour, odour and drug content.[17]
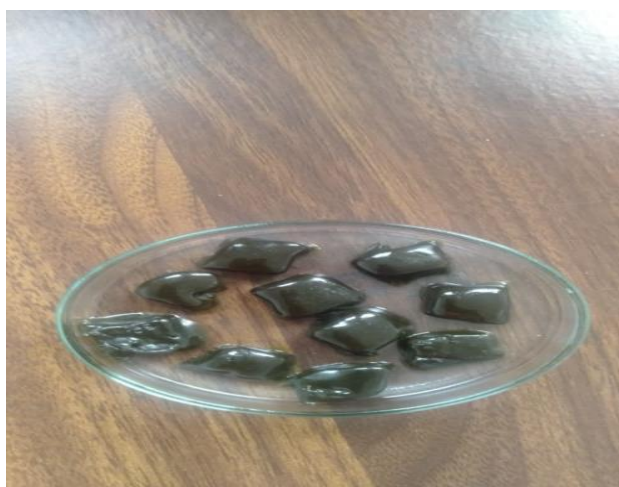

Figure :- 1 Formulation of chewing gum

Result and discussion

FT-IR

When the FT-IR spectra of guava leaves extract and F3 were compared, they showed similar characteristic peaks with minor differences. Important peaks of at 3234.10, 1047.65,2739.42, 1394.20, 667.22cm^{-1} corresponding to N-H stretching vibration in amines, C-N stretching toin amines, C-H stretching in alkane, C=C stretching vibration in aromatic compound, C-

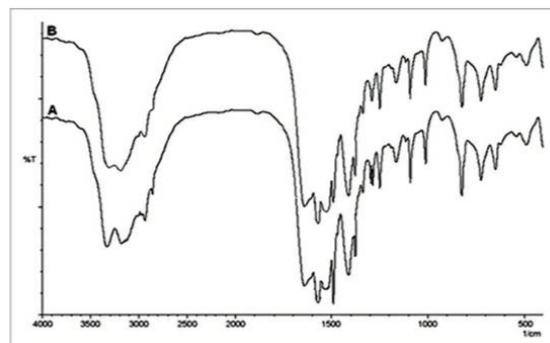CL stretching respectively remained intact in the FT-IR spectra of the F3 also.

Figure 2 - FT-IR spectroscopy spectra of guava leaves extract and formulation F3

Color of Chewing Gum

Formulated chewing gum appears to be Green in color.

Evaluation parameters of Formulation

All batches of prepared tablets were evaluated for the different parameters. Weight variation for prepared tablets was found within specifications. Average weight for tablet was in the range of 345-348mg. Thickness values for of all chewing gum were in the range of 3.50-3.71mm. Drug contents for all the formulations were found in the range of 87.24-91.26.
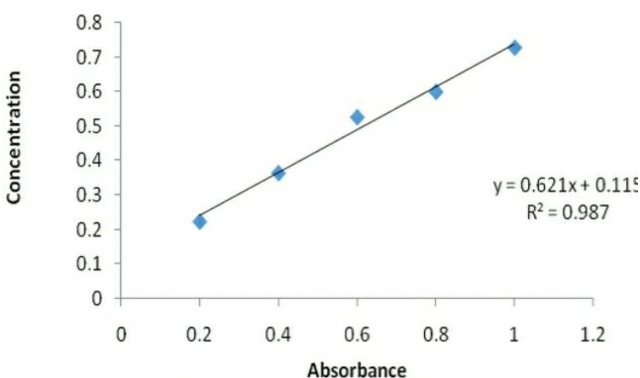
Formulations	Weight Variation(mg)
F 1	345±0.22
F 2	346±0.33
F 3	348±0.27

Table 2: Weight Variation of Chewing Gum Formulations

Formulations	Thickness(mm)
F 1	3.50±0.20
F 2	3.54±0.31
F 3	3.71±0.32

Table 3: Thickness of Chewing Gum Formulations

Formulations	Uniformity of content (%)
F 1	87.24
F 2	89.21
F 3	91.26

Table 4: Uniformity of Chewing Gum Formulations

Figure 5 – Standard calibration curve of guava leaves

Stability study of formulated chewing gum

There was no significant change was reported with the developed chewing gum in terms of colour, odour and appearance chewing gum containing guava leaves extract was able to maintain its drug content unchanged at 85.5% throughout the period of study. The study results substantiated the possibility of chewing gum as a stable formulation.

Stability studies of minimum time period	Storage conditions
15 days	0.2˚c
30 days	30±2˚c
45 days	45±2˚c

Table 6: Stability study

Discussion:

In present work formulations were prepared in the Chewing Gum form by using glycerol and gum base. This property is essential for the chewing gum base because it eliminates the possibility of dissolution of gum base in salivaFrom the results obtained in this work, it can be concluded that synthetic gum base can be used as an excellent agent for formulation of chewing gum. For Chewing Gum formulations all studies like stickiness, weight variation, friability were performed The developed chewing gums of Guava leaves extract was soft, Green in colour.

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