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FORMULATION AND EVALUATION OF MUCOADHESIVE BUCCAL PATCH OF GINGEROL

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ABSTRACT

Oral mucosal drug delivery system is widely applicable as novel site for administration of drug for immediate and controlled release action by preventing first pass metabolism. Ginger is a complex substance consisting of more than 60 compounds. Ginger is a popular herb for its culinary and medicinal value. Ginger is antiemetic by multiple mechanisms, ginger ethanolic extraction acted by inhibiting central and peripheral muscarinic and histamine-1 receptors, 5-HT3 receptor antagonist. Buccal patches were prepared with Gingerole with polymers such as Hydroxy Propyl Methyl Cellulose in a respective solvent such as Ethanol with Propylene glycol as the plasticizer and Sorbitol Liquid as sweetening agent. Buccal patches were successfully formulated by solvent casting technique with several concentrations of polymers and those prepared patches were characterized in terms of film thickness, film weight, color, surface texture, folding endurance, surface pH, swelling behavior and percentage of moisture loss.

Keyword: Ginger, Antiemetic, Gingerol, Mucoadhesive Buccal Patch

INTRODUCTION

Traditional Indian medicine is one of the oldest medical sciences in the world. Ayurveda, the most widely used system in traditional Indian medicine, emphasizes holistic medicine, which takes the body, mind, and spirit as a whole. It is based on the principle that human beings achieve physical, mental, and emotional health through harmonious coexistence with nature **[1]**.

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action by preventing first pass metabolism and enzymatic degradation due to GI microbial flora. Oral mucosal drug delivery system provides local and systemic action. The buccal mucosa lines the inner cheek, and buccal formulations are placed in the mouth between the upper gingivae (gums) and cheek to treat local and systemic conditions **[2]**.

In comparison to the skin, the buccal mucosa offers higher permeability and faster onset of drug delivery; whereas the key features which help it score over the other mucosal route, the nasal delivery system, include robustness, ease of use, and avoidance of drug metabolism and degradation **[2]**.

In comparison to TDDS, mucosal surfaces do not have a stratum corneum. Thus, the major barrier layer to transdermal drug delivery is not a factor in oral mucosal routes of administration. Hence oral mucosal systems exhibit a faster initiation and decline of delivery than transdermal patches **[2]**.

Ginger (*Zingiber officinale Roscoe*) belongs to the family *Zingiberaceae* and genus *Zingiber*. Other names of ginger are African ginger, Black ginger, Cochin ginger, GanJiang, Gegibre, Ingwer, Jamaican Ginger, and Race ginger **[3]**.

Ginger is an integral part of ayurveda, the traditional medicine of India, and is known as sunthi in Ayurveda. It was also used as a digestive aid and antinausea remedy and to treat bleeding disorders, rheumatism, baldness, toothache, snakebite, and respiratory conditions **[3]**.

Ginger is a complex substance consisting of more than 60 compounds. The ginger rhizome contains an essential oil and resin known collectively as oleoresin. The composition of the essential oil varies according to the geographical origin, but the chief constituents are sesquiterpene hydrocarbons, which are responsible for the characteristic aroma. Gingerole is the main phenolic compound and once degraded gives shogaols, zingerone, and paradol **[3]**.

Ginger (rhizome of *Zingiber officinale*) is a popular herb for its culinary and medicinal value. The pungent principles are gingerol, shogaol, zingerone and paradol. [6]-Gingerol and [6]-Shogaol are the major active components for ginger's pharmacological effects and pungency respectively **[4]**.

Ginger has been used since antiquity both as a spice and as a herbal medicine to treat a variety of primarily gastrointestinal ailments, such as nausea, vomiting (emesis), diarrhea, and dyspepsia, and also diverse ailments, including arthritis, muscular aches, and fever., ginger capsules have been available in UK for more than 40 years as a remedy for motion sickness and as a carminative. The rhizome of

ginger contains a wide variety of biologically active secondary metabolites. The rhizome comprises 1%–4% of volatile oils and an oleoresin **[5]**.

Herbal medicines have been shown to be effective antiemetics, and among the various plants studied, the rhizome of *Zingiber officinale*, commonly known as ginger, has been used as a broad-spectrum antiemetic in the various traditional systems of medicine for over 2000 years. Various preclinical and clinical studies have shown ginger to possess antiemetic effects against different emetogenic stimuli **[6]**.

MATERIAL AND METHODS

Chemical and Equipments:

Ethanolic extracts of Ginger , Hydroxy Propyl Methyl Cellulose (HPMC), Propylene glycol, Ethanol, Sorbitol liquid were used and several equipments employed in the formulation of herbal patches were, Petridish, Electronic balance, Beaker , Stirrer , Gravimetry Bottle , Funnel , Water Bath.

Plant Material:

The ginger rhizome was purchased from local market of Nandurbar. The material were cleaned & dried under shade & then placed in oven at 20-40 °C. The dried rhizomes were weighed and stored in desiccators.

Isolation of Gingerol from Ginger:

Dry ginger was crushed to a coarse powder and extracted with 95% ethanol by simple maceration process. Solvent was evaporated by distillation to obtain thick pasty mass. The thick pasty mass was suspended in water. The Ginger resin precipitates in water which was removed by filtration and the residue obtained was dried under vacuum **[7]**.

Preparation of Mucoadhesive Buccal Patches:

The technique employed for preparing mucoadhesive buccal patches was solvent casting technique. They were prepared by dissolving several concentrations of HPMC polymers such as 150mg, 300mg and 500mg in 5ml of ethanol and calculated amount of the ginger extract (40mg) was dissolved in another 5ml of ethanol and this mixture was added to the polymer mixture followed by the addition of 0.5ml of sweetening agent. Then 0.5ml of the plasticizer was added to all formulations. Then they were transferred to a petridish and allowed to dry under room temperature by placing a funnel in an inverted position over the petridish for 48 hours. After that all the patches were studied for further characterizations **[7]**. Composition of all patches is shown in **Table 1**.

Table 1: Composition of Mucoadhesive Buccal Patches

Sr. No.	Ingredients	F1	F2	F3
1	Ginger Extract	40mg	40mg	40mg
2	Hydroxy Propyl Methyl Cellulose	600mg	300mg	150mg
3	Ethanol	10ml	10ml	10ml
4	Propylene Glycol	0.5ml	0.5ml	0.5ml
5	Sorbitol Liquid	0.5ml	0.5ml	0.5ml

Characterizations of formulated Mucoadhesive Buccal patches [7]

- ✓ **Patch weight:**

  All patches were weighed on a digital weighing balance and their weights were noted.

- ✓ **Patch thickness :**

  Film thickness was measured using vernier callipers from all sides at different position and the average value was noted.

- ✓ **Surface texture :**

  Surface texture of all the patches were noted by touching the surface of the films.

- ✓ **Colour :**

  Colour of all the formulated patches was noted visually and they were reported finally.

- ✓ **Folding endurance :**

  Folding endurance of buccal patches was determined by folding each patch at the same place repeatedly until it breaks. Number of times the patches can be folded until it breaks gives the value of folding endurance and the average value was noted.

Surface pH:

Patches of 1 cm^2 each were allowed to swell in 2% agar solution in a clean, dry petridish for two hours consecutively. Surface pH of patches was determined by placing pH paper on the surface of patches

Swelling behavior:

Each patches of size (1 cm x 1cm) was cut and their initial weight was noted. Then they were allowed to swell for 5 min in 20 ml of distilled water. Patches were than taken out, dried and weighed. Percentage of swelling was noted using the following formula:

Swelling Index (SI) = Final weight - Initial weight/Initial weight x 100

- ✓ **Percentage Moisture Loss (PML) :**

  All patches of size 1 cm x 1 cm was initially weighed. They were placed in a dessicator containing Calcium chloride and the internal humidity was maintained. After 72 hours, all patches were collected back and reweighed. Average value was noted using the following formula:

Percentage Moisture Absorption (PML) = Initial weight - Final weight/Initial weight x 100

RESULTS AND DISCUSSION:

Patch weight:

Overall patches weights were found in the range of 0.02 to 0.04 mg

✓ **Patch thickness:**

Patch thickness was found in the Range of 0.10-0.08 mm

Surface texture:

Surface texture was found to be smooth for all the patches.

✓ **Colour:**

Colour of all the patches were uniformly found to be yellow.

✓ **Folding endurance:**

Folding endurance of all the patches were found to be flexible exceptionally F2 was less flexible than F1 & F3

✓ **Surface pH:**

Surface pH of all the patches were found almost neutral i.e 7-8.

✓ **Swelling behavior:**

Overall swelling index of all the patches were found to be negligible.

✓ **Percentage Moisture Loss (PML):**

Percentage of moisture loss were found to be for F1 50% and F2, F3 75%

Table 2(a): Characterizations of Mucoadhesive Buccal Patches

Sr.no.	Formulation	Patch Weight	PatchThickness	Surface Texture	Colour
1	F1	0.04±001mg	0.10mm	Smooth	Yellow
2	F2	0.04±0.01mg	0.09mm	Smooth	Yellow
3	F3	0.02±0.01mg	0.08mm	Smooth	Yellow

Table 2(b): Characterizations of Mucoadhesive Buccal patches

Sr. No	Formulation	Folding endurance	Surface pH	Swelling behavior	Percent moisture loss
1	F1	**	7	2.5%	50%
2	F2	*	7	Negligible	75%
3	F3	**	7	Negligible	75%

***Flexible **Very flexible**

CONCLUSIONS:

Ginger extract loaded mucoadhesive buccal patches were successfully formulated by several concentrations of Hydroxy Propyl Methyl Cellulose (HPMC) polymers and with propylene glycol plasticizer and with an organic solvent ethanol and were characterized. From this novel approach, it can be concluded that herbal drugs in the form of extracts can also be employed in formulating mucoadhesive patches in contrast with the usage of allopathic drugs in accordance with their appropriate concentrations and doses.

May be concluding that F1 containing Polymer HPMC was observed in preparation of mucoadhesive buccal patch of ginger extract (Gingerol). So the F1 has good polymer concentration to carry the mucoadhesive drug delivery of herbal constituent gingerol, in which is isolated from Zingiber *officinale*.

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