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Mouth Dissolving Tablets and Candies prepared from popularly Known Spices

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Abstract

Two popularly known spices were selected for the preparation of Mouth Dissolving tablets (MD tablets) and candies. MD tablets prepared from Ginger/Sunthi and Cinnamon, and candies prepared from Sunthi, in different proportions, along with citric acid were taken for the study. Physico-chemical parameters were studied, and the presence of corresponding spices in the samples, was proved by following the well-versed HPTLC technique. Safety of the products, for consumption, was assured, by carrying out microbiological evaluation. It was observed that the MD tablets and candies are medicinally valuable, due to their positive action on certain discomforts. They provide fast relief from throat infection and motion sickness, and make us feel comfortable.

Keywords: Spices, MD tablets, Candies, Ginger/Sunthi, Cinnamon, Physico-chemical parameters.

Introduction

India has been known from prehistoric times as the land of spices. Spices and herbs have tremendous importance in everyday life as ingredients in food, alcoholic beverages, medicine, perfumery, cosmetics, coloring agents, and also as gardening plants. Spices impart flavor, aroma and color and thus, they are an essential part of Indian food. Spices show a variety of health benefits including carminative action, hypolipidemic effect, antidiabetic, antilithogenic, antioxidant, anti-inflammatory, anti-mutagenic and anti-carcinogenic properties. The hypocholesterolemic and antioxidant properties have far reaching nutraceutical and therapeutic value. Most of the medicinal properties are attributed to the secondary metabolites present in spices. Hence, spices are increasingly being noticed for their pharmacological activities and therefore their potential as a functional food has tremendous scope. In Ayurveda, about 25 spices have been used for various herbal preparations[1]. Amongst all of them, ginger (sunthi) and cinnamon (taj) are very commonly used and are extremely well-known for their medicinal uses.

Zingiber officinale (Ginger/Sunthi), Family Zingiberaceae, is a spice obtained from scraped and dried rhizomes as well as green ones. It is used worldwide as a cooking spice, condiment and herbal remedy. It contains an aromatic volatile oil, having a characteristic odor and containing camphene, phellandrene, zingiberene, cineol and borneol. It also contains gingerol, an oleoresin-gingerin, K-oxalate, other resins and starch. Ginger, being aromatic and pleasantly pungent, is commonly used as a spice and in the preparation of condiments, curries and ginger bread. Also, conserves and syrups are made from fresh, young rhizomes. The Chinese have used ginger for at least 2500 years as a digestive aid and antinausea remedy and to treat bleeding disorders and rheumatism; it was also used to treat baldness, toothache, snakebite, and respiratory conditions. Dry ginger is used as a carminative adjunct along with black pepper and long pepper (Trikatu). Ginger is extremely valuable in dyspepsia, flatulence, colic, vomiting, spasms and other painful affections of the stomach and bowels, cold, cough, asthma, indigestion, increasing appetite, sore throat, hoarseness, loss of voice, diarrhoea, headache, colds and rheumatism[2].

Cinnamomum zeylanicum (Taj), Family Lauraceae, is a spice obtained from the inner bark of shoots of truncated stalks of Cinnamon trees, used worldwide, in both sweet and savoury foods. It contains volatile oils, cinnamic acid, resin, tannin, sugar, mannit, starch, mucilage, ash, cinnamyl acetate, a hydrocarbon, and small quantities of phellandrene, pinene, linalool, caryophyllene and eugenol. Cinnamon is carminative, antispasmodic, astringent, antiseptic, stomachic and germicide, diabsorbent, diuretic and demulcent. Its oil has no astringency, it is a nervine and vascular stimulant, and its volatile oils are aromatic. Its bark in the form of infusion, decoction, powder or oil, is prescribed in cold, headaches, palpitation, melancholia, dropsy, hiccough, liver complaints, diarrhoea, dyspepsia, flatulency, vomiting, cramps of stomach, enteralgia, toothache and paralysis of tongue. It is frequently employed as an adjunct to bitter tonics, purgatives and vegetable and mineral astringents, as a stimulant of the uterine muscular fiber in menorrhagia[3]. Jitareanu et[4] al evaluated the antimicrobial and antioxidant properties of cinnamic acid and its derivatives. Also, Sessou et al[5] have studied the anti-fungal activities of essential oils of Cinnamon leaves.

Both these spices are available in different forms, and are used in the treatment of various discomforts, especially throat infections, motion sickness, nausea and vomiting. *Zingiber officinale* (Ginger/Sunthi) is available in numerous forms like raw ginger root, powdered ginger (sunthi powder), sunthi

extract, pills, tablets, capsules, chewable tablets, pickled ginger, ginger cookies and biscuits. Similarly, *Cinnamomum zeylanicum* (Taj) is also found in various forms like raw bark, taj powder, taj extract, taj oil and numerous formulations can be prepared by using these active pharmaceutical ingredients (API).

Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs[6]. It has wide acceptance and popularity of up to 50-60% of solid dosage forms due to its natural, uncomplicated, convenient ease of administration, accurate dosage, self medication, pain avoidance and most importantly patient compliance[7]. In the recent trend of oral dosage forms that focuses on the ease of medication, Mouth Dissolving tablet formulation is emerging and gaining popularity because it is easy to administer and leads to better patient compliance[8]. These tablets disintegrate in the oral cavity within less than three minutes, disperse or dissolve in the saliva, leaving an easy-to-swallow residue. The drug is released immediately after contact with the saliva, thus obviating the need of water during administration. Mouth Dissolving tablets have numerous other advantages like pleasant mouth feel and acceptable taste masking property. These tablets can be administered to patients, who cannot swallow, such as small children, elderly, bedridden, disabled patients as well as patients affected by renal failure or pediatric, geriatric and psychiatric patients. Also, they are convenient for travelers and busy people who do not have access to water, continuously. The bioavailability of this dosage form is rapid, due to pre-gastric absorption from mouth, pharynx and oesophagus[8]. Thus, we get an immediate effect and fast relief by consuming the mouth dissolving form of dosage. Mathew et al[9] have designed and developed similar fast melting (mouth dissolving) tablets of Terbutaline Sulphate against bronchial asthma. Similarly, another popular oral dosage form is candy, where the fast relief effect is more persistent because the drug is kept in the mouth for a long period of time, and the drug slowly mixes with the saliva due to which the effect of candies is long-term. This type of dosage form is very useful while travelling, in case of motion sickness, nausea and vomiting. Also, in throat infections, the candy can be kept in the mouth for a long period, so that the drug slowly shows its activity on the infected area and comforts the patient.

Thus, these two oral dosage forms, Mouth Dissolving tablets and candies, that were prepared from Ginger/Sunthi and Cinnamon, were analyzed for their physico-chemical properties, to prove their consumable status. The presence of the corresponding spices was qualitatively confirmed by using the HPTLC technique. Additionally, microbiological analysis was carried out to prove that the drugs are safe for consumption.

Material and Methods

Description: The sample (MD tablets/candies) was spread in a clean, previously dried Petri dish and visually observed with the naked eyes. The color and nature (form) of the sample was recorded.

Average Weight: Twenty MD tablets/candies were accurately weighed on a suitable, previously calibrated balance and their average weight was recorded.

Disintegration Time[10]: Six MD tablets were put in a suitable disintegration time machine along with sliding discs. The temperature of water was maintained at 25°C. The disintegration machine was switched on and the time required o disintegrate all the 6 MD tablets, was recorded.

Loss On Drying at 105°C[11]: About 1g of uniformly crushed sample was weighed in an LOD bottle. The sample was dried at 105°C for about 6 to 7 hours, cooled to room temperature in a desiccator and weighed till constant weight.

pH of 1.00% w/v solution[11]: About 1 g of uniformly crushed sample was dissolved in 100 ml water, and the pH was recorded on a suitable, previously calibrated pH meter.

Content of Citric Acid[12]: 1g of uniformly crushed sample was subjected to titrimetric method mentioned in IP.

Hardness: The hardness of 5 MD tablets in kg/cm^2 was tested by using the tablet hardness tester and the average hardness was recorded.

Friability: Twenty tablets were weighed and put in a friability machine. The machine was revolved for 100 strokes (4 minutes). After 4 minutes, those 20 tablets were weighed again and the friability was calculated as follows: Friability in % (w/w) = [(x – y) X 100] / x.

Where, x = initial weight of 20 tablets in g, y = weight of 20 tablets after 100 strokes in g

Identification (HPTLC Fingerprinting): Stationary phase→TLC Aluminium sheets silica gel 60 F 254, Sample Volume → 10 microlitre, Saturation time→ 20 minutes, Spotting level→ 1cm, Time of Run→ 20 minutes, Length of Run→ 8cm, Evaluation→ Peak height and area, Detection (Spraying agent) →Vanillin sulphuric acid reagent.

Note: For Cinnamon MD tablet: Powder of 1 tablet, extracted in 10ml methanol, Solvent system used was toluene : ethyl acetate (7 : 3)

For Ginger MD tablet: Powder of 1 tablet, extracted in 10ml methanol. Solvent system used was n-hexane : ether (4 : 6). For Ginger candy: 1g of crushed candy, extracted in 5ml methanol. Solvent system used was diethyl ether : hexane (7 : 3)

Corresponding reference standards were prepared by using respective extracts/oleoresin (as mentioned in the formula) and extracted in the similar manner in methanol.

Microbiology: As per USP/BP Guidelines.

Results and Discussion

Table-1 shows formulation details with respect to composition of both mouth dissolving tablets under study, where extract powders of respective product are used for formulating these tablets.

Before manufacturing ginger candies, different concentrations of ginger were tried in extract powder form as well as in oleoresin form. Tongometric evaluation of each trial is recorded in table-2.

Since the base of the candy is semisolid sticky mass, uniform distribution of ginger powder is not possible. Hence powder form of ginger is replaced by oleoresin. Finally, ginger candies prepared from 0.25% and 0.50% ginger oleoresin are selected for the study, as they are found to be good in taste.

Candies are manufactured as per the formulae given in table-3. Each candy is of about 3g and oval in shape. Citric acid is added to reduce the pungency imparted by different constituents present in ginger.

Table-4 gives a clear picture of physicochemical tests carried out on mouth dissolving tablets. Disintegration time recorded is less than 3 minutes, as per the pharmacoepoeia. The presence of corresponding spices is recorded in respective tablets on the basis of HPTLC fingerprinting. Microbiological load is within specification which indicates the safe status for intake.

Table-5 focuses on physicochemical parameters of ginger candies, Citric acid plays an important role as the taste of the candy is more significant. Hence content of citric acid is recorded quantitatively. The content matches with the theoretical value equivalent to 46.50 mg/candy with respect to the actual formula given in table-3. pH is found to be acidic, about 2.92 and 3.10. HPTLC fingerprinting proves the presence of ginger in the product and microbiological results are found to be well within the limits specified in the USP/BP.

Figure-1 indicates the presence of cinnamon extract in cinnamon MD tablet. It shows dark spots at Rf about 0.78, 0.85, and 0.91. After spraying the plate with the spraying agent, yellow colored spots are observed at Rf 0.78 in both sample and reference extracts used.

Figure-2 evaluates the qualitative presence of ginger in Mouth Dissolving ginger tablets and in both the ginger candies. Violet colored spots are seen at Rf 0.29, and 0.61, after spraying the plate with the spraying agent.

Table-1
Formulation details "Mouth Dissolving Tablets", namely Cinnamon tablet and Ginger (Sunthi) tablet

Cinnamon Tablet	**Ginger (Sunthi) Tablet**
Each tablet of 500mg	Each tablet of 540mg
Composition : Each uncoated tablet contains : ***Cinnamomum zeylanicum*** extract powder ….. … ……..50mg Excipients … q.s.	Composition : Each uncoated tablet contains : ***Zingiber officinale*** extract powder……30 mg Citric acid ……..12.60 mg Excipients … q.s.

Table-2
Tongometric evaluation of Ginger (Sunthi) candy with different concentrations of ginger

Sr.No.	**Ginger (Sunthi) candy formulations**	**Record of tongometric evaluation**
1	Ginger extract powder….. 0.500% Sugar …… 65.00% Liquid glucose ……. 35.00% Citric acid …… 2.00%	Lack of homogeneity due to improper mixing of all the ingredients.
2	Ginger oleoresin …….. 0.200% Sugar …… 65.00% Liquid glucose ……. 35.00% Citric acid …… 1.500%	Good in taste: but seems to be mild
3	Ginger oleoresin …….. 0.250% Sugar …… 65.00% Liquid glucose ……. 35.00% Citric acid …… 1.500%	Good Product with respect to the taste factor …Better compared to sample number 1 and 2
4	Ginger oleoresin …….. 0.500% Sugar …… 65.00% Liquid glucose ……. 35.00% Citric acid …… 1.500%	Good Product with respect to the taste factor …Best among the four samples

Table–3
Formulation details of "Ginger (Sunthi)"candy

Sr.No.		Ginger (Sunthi)Candy 0.25%	Ginger (Sunthi)Candy 0.50%
	Ingredients	Quantity in mg per candy of about 3g	Quantity in mg per candy of about 3g
1	Ginger oleoresin	7.50	15.00
2	Sugar	1908	1905
3	Liquid Glucose	1029	1026
4	Citric acid	46.50	46.50
5	Spearmint	12.00	9.00
	Total	3000.00 mg	3001.50mg

Table–4
Physicochemical evaluation of Mouth Dissolving tablets

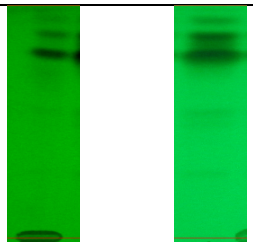
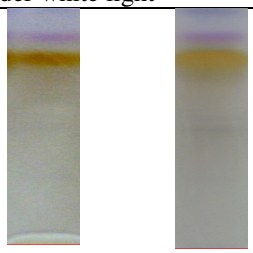
Sr.No.	Test parameters	Cinnamon Tablet	Ginger (Sunthi) Tablet
1	Description	White colored capsule shaped tablet with characteristic odor	Off white colored capsule shaped tablet with characteristic odor
2	Average weight of 20 tablets	502 .00 mg	553.90 mg
2	Disintegration Time	1 min, 90 seconds	1min. 10 seconds
3	Loss On Drying at 105^0C	4.90% w/w	5.21% w/w
4	pH of 1.00%w/v solution in water	5.72	4.19
5	Hardness	3.50 Kg/cm^2	3.00 Kg/cm^2
6	Friability	0.50% w/w	0.89%w/w
7	HPTLC Fingerprinting	Presence of Cinnamon - Positive	Presence of Gingerol-Positive
8	Microbiological Testing (As per USP / BP Specifications)		
i)	Total aerobic microbial count	10 cfu/g	20 cfu/g
ii)	Total combined yeast / moulds count	<10 cfu/g	<10 cfu/g
iii)	Bile Tolerant Gram Negative bacteria	<10 cfu/g	<10 cfu/g
iv)	*Escherichia coli*	Absent	Absent
v)	*Salmonellae spp*	Absent	Absent
vi)	*Staphylococcus aureus*	Absent	Absent
vii)	*Pseudomonas aeruginosa*	Absent	Absent
viii)	*Clostridium spp*	Absent	Absent

Cfu : Colony Forming Unit

Table-5
Physicochemical evaluation of Ginger (Sunthi) candies

Sr.No.	Test Parameters	Ginger candy 0.25%w/w	Ginger candy 0.50%w/w
1	Description	Pale yellow colored translucent, oval shaped candy	Light yellow colored translucent, oval shaped candy
2	Average weight of 20 candies	3.08g	3.10g
3	Loss On Drying at 105^0C	1.91%w/w	1.26%w/w
4	pH of 1.00%w/v Solution	2.92	3.10
5	Content of citric acid	47.33 mg//candy	45.65 mg/candy
6	HPTLC Fingerprinting - Presence of Ginger	Positive	Positive
7	Microbiological Testing (As per USP/BP specifications)		
i)	Total aerobic microbial count	110 cfu/g	10 cfu/g
ii)	Total combined yeast / moulds count	10 cfu/g	10 cfu/g
iii)	Bile Tolerant Gram Negative bacteria	<10 cfu/g	<10 cfu/g
iv)	*Escherichia coli*	<10 cfu/g	<10 cfu/g
v)	*Salmonellae spp*	Absent	Absent
vi)	*Staphylococcus aureus*	Absent	Absent
vii)	*Pseudomonas aeruginosa*	Absent	Absent
viii)	*Clostridium spp*	Absent	Absent

NMT : Not More Than Cfu : Colony Forming Unit

Under 254nm	After spraying and observing under white light	Observation
		1 Cinnamon MD tablet 2 Cinnamon extract Solvent system used - toluene:ethyl acetate (7 : 3) Under 254nm: Dark spots at Rf's 0.78, 0.85 and 0.91. After spraying and observing under white light: Yellow spot at Rf 0.78

Figure—1
HPTLC Fingerprinting of Cinnamon MD tablets

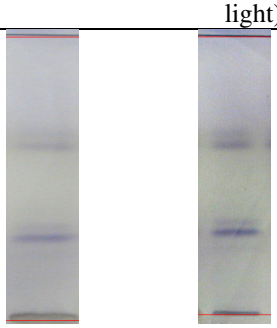
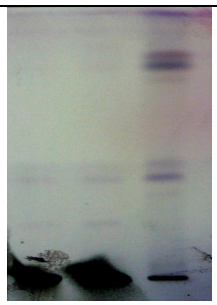
Ginger MD tablets (after spraying and observing under white light)	Ginger candy (after spraying and observing under white light)
	 1 2 3
1 Ginger MD tablet 2 Ginger (sunthi) extract Solvent system used was n-hexane : ether (4 : 6) After spraying and observing under white light: Violet spots at Rf's 0.29 and 0.61	1 = Ginger candy (0.25%) 2 = Ginger candy (0.50%) 3 = Ginger oleoresin Solvent system used was diethyl ether : hexane (7 : 3) After spraying and observing under white light: Violet spots at Rf's 0.29 and 0.61

Figure-2
HPTLC Fingerprinting of Ginger MD tablets and Ginger candy

Conclusion

Most popularly used spices in the food, namely cinnamon and ginger, are easily available, less expensive and medicinally useful. Spices with different medicinal values can be used for formulating Mouth Dissolving tablet formulation as it gives instant desired effect of the medicament. The bioavailability of cinnamon and ginger, can be effectively achieved, by consuming them in mouth dissolving tablets form. Ginger candies are good in taste and impart good, long lasting remedies for many discomforts. Also, since it remains for a long time, in the mouth it has pleasant, long-term effect. Both, Mouth Dissolving tablet and candy formulations can be easily consumed by people of any age, for fast and better relief from irritations like nausea, vomiting, throat infections and motion sickness to make us feel comfortable.

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