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PREPARATION AND EVALUATION OF TOOTHPASTE CONTAINING RIBOFLAVIN

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ABSTRACT

The present work deals with the formulation and evaluation of tooth paste containing riboflavin for preventing occurrence of mouth ulcers. Different formulations were prepared using varying concentration of abrasive calcium carbonate and humectant glycerin. All formulations were evaluated for various parameters like dryness, colour, appearance, consistency, pH, spreadability and foaming capacity. The formulations were optimized based on these evaluation studies and formulation F8 was found to be the best showing yellow opaque colour, pleasant appearance with paste like consistency, neutral pH, good spreadability and foaming capacity.

1. Introduction

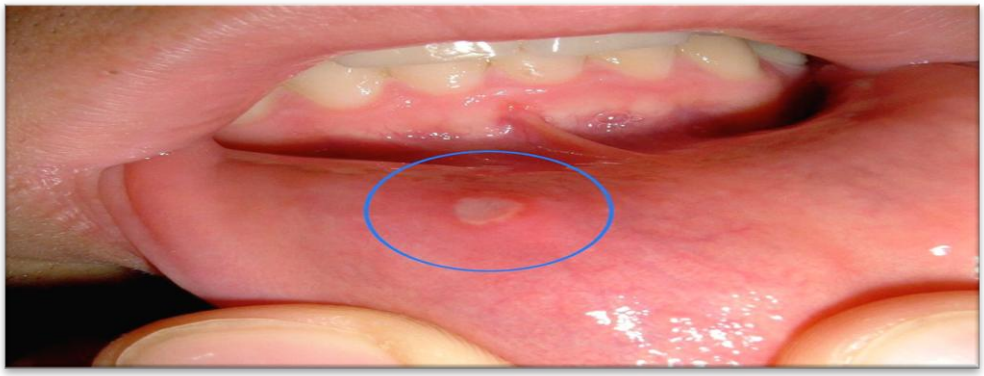
Toothpaste containing riboflavin (F1- F9) were formulated using calcium carbonate as abrasive and Glycerin as humectant in varied concentrations based on factorial design. When used with a toothbrushthe primary function of a dentifrice is to clean of the surface of the teeth. A dentifrice helps in the removal of food particles, reduction of superficial plaque or stain, polishing of tooth surface and refreshing mouth breath. Therapeutics & cosmetic functions may be desired, such as whitening, bleaching, desensitizing, inhibition of plaque formation and protection against periodontal problems[2]. Buccal mucosa shows good permeability to drugs. Therefore incorporating drugs in toothpaste may be used for better drug absorption.

Dentifrices are disperse systems. They consist of water and water soluble liquids, oils and both soluble and insoluble solids. As such they are dispersions of solids in a liquid vehicle. Important characteristic of toothpaste are consistency, abrasiveness, appearance, foaming, taste, stability and safety. Most commonly ingredients used in toothpaste formulation are Active pharmaceutical ingredients, abrasives, humectants, detergents, binders, sweeteners, preservatives and antioxidants[3].

Historically the need and desirability of cleaning the teeth paralleled the recognition of the necessity to maintain bodily cleanliness. Many of the materials used and recipes suggested, however, contained materials capable of damaging the teeth and gums. The modern world therefore had a real social, medical and aesthetic need for well formulated, safe and effective dentifrices. Toothpaste is the daily used material for cleansing the teeth and to provide freshness to mouth. The rationale behind making herbal toothpaste is to fight against the bacteria that cause problems regarding to teeth like gum, dental cavity and gingivitis.

The present work deals with development and evaluation of toothpaste containing riboflavin. Riboflavin is vitamin B2, deficiency of which causes precipitation of mouth ulcer[4,5].

Figure1. Mouth ulcer



Materials and Methods

Materials

The materials used in the preparation of toothpaste was obtained from Chemdyes corporation, Rajkot.

Preparation of toothpaste

For designing of the experimental work, 32 factorial designs were used. Factors selected were concentration of abrasive and concentration of humectant and levels chosen were low (-1), medium (0) and high (+1) and were shown in Table 1.

Table 1. Level based design of the batches as per factorial design

Factors	Concentration of Abrasive	Concentration of Humectant(glycerin)
Levels		
Low	-1	-1
Medium	0	0
High	+1	+1

Table 2. Developed formulations from F1-F9 as per factorial design

Formulation code	Abrasive	Humectant
F1	-1	-1
F2	0	-1
F3	1	-1
F4	-1	0
F5	0	0
F6	1	0
F7	-1	1
F8	0	1
F9	1	1

Different formulations of the toothpaste were developed according to the Table 3.All the powder materials were passed through 60# sieve. Firstly gum is mixed with humectant for proper dispersion. Other powdered ingredients are sifted together and mixed gradually to mucilaginous mixture with continuous gentle stirring. The aqueous media is mixed and stirred to get product. Flavours and detergent are added at last and then it is packed[2].

Table 3. Composition of the formulations: (all quantity in %w/w)

Ingredients	Quantity taken per 100 gm paste (in grams)								
Formulation code	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Riboflavin	1	1	1	1	1	1	1	1	1
Calcium carbonate	34.5	34.5	34.5	44.5	44.5	44.5	54.5	54.5	54.5
Magnesium carbonate	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Magnesium hydroxide	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Sodium lauryl sulphate	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Tragacanth	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Glycerin	11	21	31	11	21	31	11	21	31
Peppermint oil	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Saccharin	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01	0.01
Water	47.4	37.4	27.4	37.4	27.4	17.4	27.4	17.4	7.4
Propyl paraben	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Evaluation of Formulations[6,7,8]

Drying tendency

General Evaluation of tooth paste was done on the basis of drying tendency of the prepared formulations (F1 – F9) at room temperature for a week and the drying tendency was noted.

Organoleptic Characters

All the formulations were characterized on the basis of organoleptic characters like appearance, colour, texture, after taste and extrudability.

Physicochemical Parameters

Determination of grittiness

The paste was extruded about 15 to 20 mm length from collapsible tube of each sample on a butter paper. Then all the samples were tested by pressing it along its entire length by a finger for the presence of hard and sharp edged abrasive particles.

Determination of pH

The net quantity of 5 gm of sample was accurately weighed and placed in a 150 ml beaker. To this 45 ml of freshly boiled and cooled water was added at 27°C. It was stirred well to make a thorough suspension. The pH was determined within 5 minutes by using pH meter.

Determination of foaming power

About 5gm of sample was accurately weighed and placed in a 100 ml glass beaker. To this10 ml of water was added and the beaker was covered with a watch glass and allowed to stand for 30

minutes. This operation was carried out to disperse the toothpaste in water. The contents of the beaker were stirred with a glass rod and the slurry was transferred to a 250 ml graduated measuring cylinder, during this transfer ensured that no foam was produced and no lump paste went into the measuring cylinder. The residue left in the beaker was transferred with further portion of 5- 6 ml of water to the cylinder. The content of cylinder was adjusted to 50ml by adding sufficient water. Stirred the contents of the cylinder with a glass rod to ensure a uniform suspension.The cylinder was stoppered and 12 complete shakes were given to it. The cylinder was allowed to stand for 5 minutes and the volume of foam with water (V1) and water only (V2) was noted for all samples.

Determination of foaming power:

$$Foaming\ power = V1 - V2$$

V1 - Volume in ml of foam with water.

V2 - Volume in ml of water only.

Optimization of formulations

Optimizations of the prepared formulations were done on the basis of drying tendency and consistency. Then test for drug content was performed for the selected formulations of toothpaste.

Determination of drug content

The drug content of formulations F6, F8, F9 was determined by UV-spectrophotometry.

Determination of $\lambda_{max:}$ Preparation of Stock Solution: Standard stock solution of Riboflavin was prepared by dissolving 100mg of Riboflavin in 100ml of 0.1N NaOH which gives 1000ppm concentration. 10ml of this stock solution was taken and was diluted up to 100ml by using 0.1N NaOH to produce a concentration of 100ppm solution.

Preparation of Working Standard: From the above stock solution 1.5ml pipetted in to 10ml volumetric flask and the volume was made up with 0.1N NaOH to produce concentration of 15ppm. The solution was scanned in UV-Visible spectrophotometer in the range 600nm-400nm using 0.1N NaOH as a blank. The wavelength corresponding to maximum absorbance (λ_{max}) was found at 445 nm.

Preparation of Calibration Curve: 0.5ml solution of 100ppm was diluted to 10ml to produce 5ppm solution. 1ml, 1.5ml, 2ml, 2.5ml, 3ml of 100ppm solution was diluted to 10ml with 0.1N NaOH to produce 10ppm, 15ppm, 20ppm, 25ppm, 30ppm respectively. Thus calibration curve was constructed by taking solution concentrations ranged from 5ppm-30ppm. The calibration curve was plotted by taking concentration on X-axis and absorbance on Y-axis[9].

Determination of drug content:1g paste was taken in a beaker and dispersed in 100 ml of 0.1 N NaOH. Then it was filtered and the filtrate was collected. 1 ml of this filtrate was pipetted to a 10 ml volumetric flask and made up the volume with 0.1 N NaOH. This sample was then analyzed using UV spectrometer at 445 nm.

3. Results and Discussion

The optimization of the toothpaste was done on the basis of consistency and drying tendency. Table 4 showed drying tendency of formulations F1 - F9. Characterization of the selected batches was done on the basis of different organoleptic characters like color, appearance, extrudability and surface feelings. The data are shown in Table 5. All formulations except F4, F7 and F9 passed the test for drying tendency but only formulations F7, F8, F9 have paste like consistency. Therefore formulation F8 was met the criteria of acceptableformulation.

Table 4. Evaluation of the toothpaste base on the basis of drying tendency

Formulation code	Drying tendency
F1	Not dried
F2	Not dried
F3	Not dried
F4	Dried
F5	Not dried
F6	Not dried
F7	Dried
F8	Not dried
F9	Dried

Table 5.Evaluation of the toothpaste on basis of organoleptic characters.

Formulation code	Organoleptic character				
	colour	**Appearance**	**Extrudability**	**Texture**	**Fragrance**
F1	Yellow opaque	Liquid dispersion	Easy	Smooth	Mint like
F2	Yellow opaque	Liquid dispersion	Easy	Smooth	Mint like
F3	Yellow opaque	Liquid dispersion	Easy	Smooth	Mint like
F4	Yellow	Liquid	Easy	Smooth	Mint like

	opaque	dispersion			
F5	Yellow opaque	creamy	Easy	Smooth	Mint like
F6	Yellow opaque	Creamy	Easy	Smooth	Mint like
F7	Yellow opaque	Paste	Easy	Smooth	Mint like
F8	Yellow opaque	Paste	Easy	Smooth	Mint like
F9	Yellow opaque	Paste	Easy	Smooth	Mint like

Table 6.Evaluation of physicochemical parameters

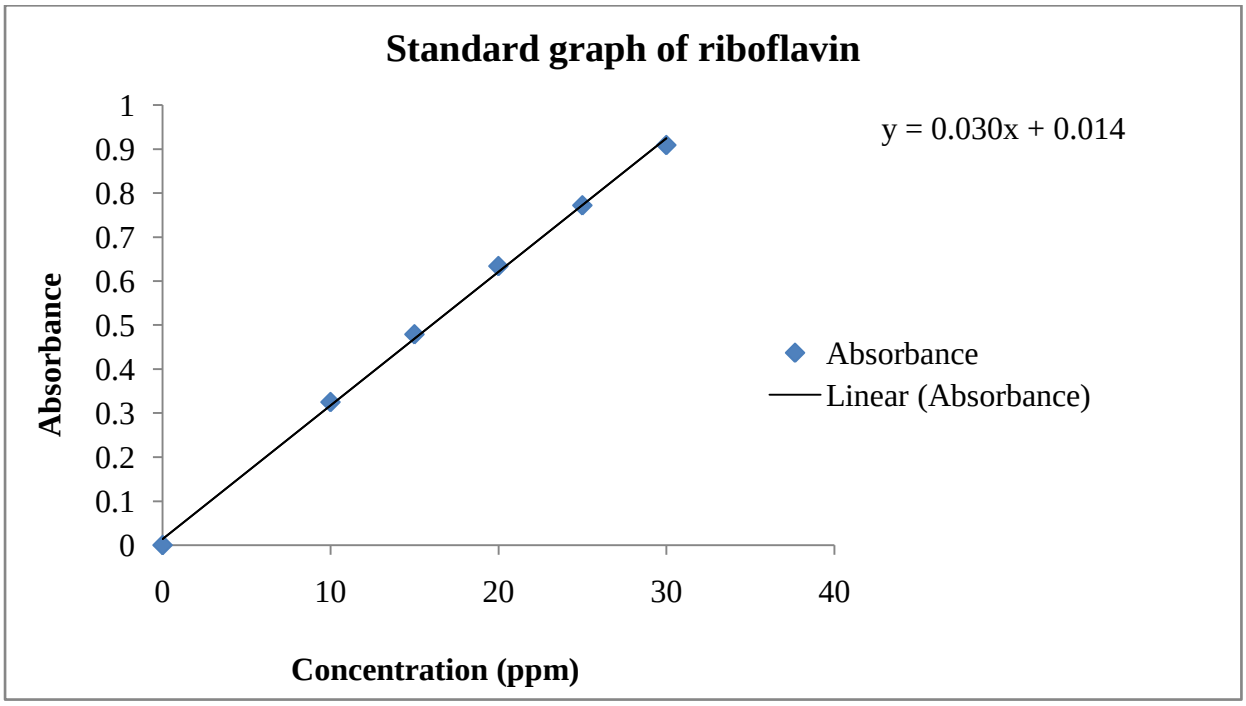
Formulation code	Grittiness	pH	Foaming capacity	Spreadability
F1	Absent	7	38	Easily spreadable
F2	Absent	7	52	Easily spreadable
F3	Absent	7	45	Easily spreadable
F4	Absent	7	41	Easily spreadable
F5	Absent	7	41	Easily spreadable
F6	Absent	7	38	Easily spreadable
F7	Absent	7	49	Easily spreadable
F8	Absent	7	52	Easily spreadable
F9	Absent	7	52	Easily spreadable

Drug content

Table 7.Calibration data of riboflavin

Concentration	Absorbance
0	0
10	0.325
15	0.479
20	0.634
25	0.772
30	0.909

Figure2. Calibration curve of riboflavin



The concentration of riboflavin in formulation F8 was obtained from the standard graph of riboflavin. The drug content in formulation F8 was found to be 98.6%.

Conclusion

According to the present study formulating toothpaste containing riboflavin may be used to prevent occurrence of mouth ulcer due to vitamin B_2 deficiency. The prepared formulation F8 exhibited good characteristics. But additional studies must be conducted to evaluate the permeation of riboflavin through buccal mucosa.

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