Formulation, Development and evaluation of Effervescent Tooth Tablet of Biomin F

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Abstract: The research aimed to develop Effervescent tooth tablet using Biomin F as an active ingredient along with excipients. The tooth tablet was formulated to maintain oral hygiene, prevent tooth decay, and exhibit antibacterial properties. The main aim is to provide a convenient and effective oral care solution, alternative to toothpaste. The tooth tablet showed a white color and significant tooth whitening, reduce hypersensitivity and prevent plaque and antibacterial activity against acid producing bacteria. The research concluded that the tooth tablet had potential for dental health, showing promising results in terms of hypersensitivity, tooth whitening, antibacterial activity and formulation stability. In present work an attempt has been made to formulate an effervescent tablet containing immediate release of Biomin F using various acids and bases. In the preformulation study, compatibility evaluation was performed which implies that drug; acids, bases and other excipient are compatible with each other. The formulation of tablets was done by using direct compression method which was found acceptable. The total 4 batches were prepared and evaluated for hardness, disintegration time, weight variation and solubility. All the formulation shows hardness and weight variation with in limit but the combination of citric acid (16.2%), sodium bicarbonate (16.2%) for the formulation (F1) because these shows the good effervescent reaction and has no problem in capping and sticking like other formulation.

Keywords: Oral hygiene, Dental, Antimicrobial, Tooth tablet, effervescent etc.

A. Introduction:

Bioactive glass (BAG) is a biomaterial commonly used in dentistry due to its biocompatibility, bioactivity, and antimicrobial properties. The original bioactive glass, later known as Bioglass 45S5®, was developed by Larry Hench at the University of Florida in 1969.Since its approval by the Food and Drug Administration (FDA) in 1985, it is estimated that Bioglass® 45S5 has been used to repair bone and tooth defects in more than 1.5 million patients. Dentin hypersensitivity (DH) is a common condition, with a prevalence of 10 to 30% in the general population, making it one of the main issues in dental practice. The agony manifests suddenly, yet is sustained for a long period of time by a sizable proportion of patients.

In recent years, there has been a significant shift toward more sustainable and eco-conscious personal care products. Among these innovations, effervescent tooth tablets have emerged as a promising alternative to conventional toothpaste. These small, chewable tablets are designed to offer the same level of oral hygiene as toothpaste, but with several added benefits that align with modern environmental and lifestyle concerns.

Effervescent tooth tablets are formulated with ingredients similar to those found in traditional toothpaste, such as gentle abrasives, fluoride or natural remineralizing agents, sweeteners like xylitol, and essential oils for fresh breath. However, instead of being dispensed from a plastic tube, these ingredients are compressed into solid tablet form. When chewed, the tablets react with saliva—or a small sip of water—creating a gentle fizzing action through the interaction of substances like citric acid and sodium bicarbonate. This effervescence helps to distribute the

active ingredients throughout the mouth, aiding in the cleaning process and giving users a refreshing, foaming experience similar to that of toothpaste.

For personal care items in their purchases, consumers place a high value on sustainability and clean label attributes. Retailers' shelves are stocked with reusable and environmentally friendly products. Traditional toothpaste tubes, on the other hand, are harmful to the environment, owing to the packaging materials used. The tubes are constructed of aluminum and plastic, and they take a lot of time, labor, and recycling to produce. Toothpaste tubes break down into microplastics over time, posing a risk to the environment as well as human and animal health. As a result, toothpaste tablets are emerging as a practical solution. Toothpaste tablets are small, bite-sized chewable that can be chewed into a paste before brushing, and they're showing a similar effect as traditional toothpaste. Toothpaste tablets make use of toothpaste formulations, including xylitol, calcium carbonate, sodium bicarbonate, and tartaric acid derivatives, without the addition of water. They are packed in a close manner to medicinal pills. Toothpaste tablets are available in both fluoride and non-fluoride formulations, also are free of preservatives such as parabens, and can have a long shelf life inadequate storage conditions. The product can be popular among users looking for natural products.

These products are beneficial in terms of portability and resistance to temperature changes. Therefore, users don't have to carry around bulky toothpaste tubes, and need not worry about the paste going dry when they forget to close the cap. Toothpaste tablets are a good option for maintaining oral hygiene levels while traveling. The containers can be easily stored in small bags, and users can use them even without a toothbrush for a fast cleansing.

Toothpaste tablets are still not well known among purchasers and they're not easily available at large retailers. Also, toothpaste tablets have not yet been approved by organizations such as the American Dental Association due to a lack of adequate clinical trial data. Fluoride-free products do not have a very good reputation in the oral care sector due to the potential for an increased risk of cavities and also, consumers may not be comfortable making the change from toothpaste to tablets.

B. Material and methods:

1. Material:

Table 1: List of Materials

Sr. No.	Ingredients	Specification	Manufacturer
1	Biomin F	-	Nano Research Lab
2	Xylitol	BP	Herboveda India
3	Citric Acid	BP	Loba Chemie Pvt. Ltd.
4	Cross Carmellose Sodium	BP	J.R. Drug Chem
5	Microcrystalline cellulose Powder	BP	J.R. Drug Chem
6	Sodium Bicarbonate	BP	Loba Chemie Pvt. Ltd.
7	Natural Peppermint	BP	Gaurav Enterprises
8	Colloidal Silicon Dioxide	BP	Par Drugs
9	Magnesium Stearate	BP	J.R. Drug Chem

2. Method: Effervescent tooth tablet were prepared by direct compression method. The tooth tablet were characterized by Physical appearance, hardness, thickness, friability, average weight, Fourier infra-red spectroscopic (FTIR) and Scanning electron microscopy (SEM), disintegration time, effervescence time was done.

C. Spectroscopy Study:

1. U.V spectroscopy

1. Standard stock solution: 1.00 mg/ml (1000 µg/ml) dissolve 100.0 mg in methanol and make up to 100.0 mL.
2. Intermediate stock: 100 µg/ml dilute 1.0 mL of 1000 µg/ml stock to 10.0 ml with solvent.
3. Wavelength for measurement (λmax): By taking absorbance in the range 200nm - 350nm on UV spectrophotometer, we determined the maximum wavelength (λ_{max}).

2. Transmission Electron Microscopy: It represents the particle size of drug. Particle Size: Less than 200 µm.

3. X-ray Diffraction: XRD pattern of drug shows peak between 20-30 degree represents the amorphous nature of the material.

4. Scanning electron microscopy: SEM shows the spherical morphology of drug

5. EDAX Analysis: EDAX is use to study the composition present in bioactive material

6. Drug excipient compatibility study: Drug - excipients compatibility study was carried out by keeping API alone and along with the excipients in clear transparent glass vials stopper with LDPE plugs with holes. The samples were kept at 40°C / 75% RH for 4 weeks and evaluated for impurity and appearance at initial and 4th week.

The compatibility studies provide the frame work for the drugs combination with the excipients in the fabrication of the dosage form. The study was carried out to establish that the therapeutically active drug has not undergone any changes, after it has been subjected to processing steps during formulation of tablets.

D. Formulation of effervescent tooth tablet

1. The API, Cross carmellose Sodium, xylitol, Sodium Bi carbonate and Citric Acid was sifted through #40 S.S. Sieve &.Collected in Polyline Container, mixed properly.
2. Adsorb the Natural peppermint in MCCP and Colloidal silicon dioxide, was sifted through #40 S.S.Sieve, then sifted materials is added to the blend (1).
3. The Magnesium Stearate was sifted through #60 S.S.Sieve & then mixed with the blend (2).
4. The lubricated blend were compressed using compression machine fitted with 7.0 × 3.1 mm round shaped slightly biconvex plain on one side and have breakline on other side of each tablet punches.

Table 2: Formulation variables of Effervescent tooth tablet

Sr. No.	Chemicals (Excipients)	F1 (mg/tab)	F2 (mg/tab)	F3 (mg/tab)	F4 (mg/tab)
1	Biomin F	75	75	75	75
2	Xylitol	37.5	37.5	37.5	37.5
3	Citric Acid	40.5	35.2	55.8	29.6
4	Cross Carmellose Sodium	6.8	7	6	6
5	MCCP	45.5	55	40.5	41.4
6	Sodium Bi carbonate	40.5	35.2	30	56
7	Natural Peppermint	0.2	0.1	0.2	0.5
8	Colloidal Silicon Dioxide	2	3	3	2
9	Magnesium Stearate	2	2	2	2
	Total	250	250	250	250

E. Pre-formulation study:

1. Bulk Density: It refers to a measurement to describe packing of particles. Bulk density is used to determine the amount of drug that occupies the volume in gm/ml.

$$Pi = m/vi$$

2. Tapped Density: Weighed quantity of API was taken into a graduated cylinder. Volume occupied by Drug was noted down. Then the cylinder was subjected to 500, 750 & 1250 taps in tap density tester (Electro Lab USP II). According to USP, the blend was subjected for 500 taps. % Volume variation was calculated and subjected for additional 750 taps. % Variation is calculated.

$$Pt= m/vt$$

3. Compressibility Index: Weighed API was transferred to 100ml-graduated cylinder and subjected to 500,750&1250 taps in tap density tester (Electro lab). The difference between two taps should be less than 2%. The %of compressibility index calculated using formula,

$$CI = vi –vt/ vi x 100$$

4. Hausner's Ratio: It is measurement of frictional resistance of the drug. The ideal range should be 1.2 –1.5.it is the determined by the ratio of tapped density and bulk density.

Hausner's ratio = vi/ vt

5. Angle of Repose: The angle of repose has been used to characterize the flow properties of solids. Angle of repose is a characteristic related to interparticulate friction or resistance to movement between particles.

$$\Theta = \tan^{-1} (h/r)$$

F. Evaluation of Effervescent tooth tablet:

1. Physical appearance: Consumer acceptability of tablets depends critically on their overall elegance, visual identity, and general appeal. Tablet size, form, color, taste, odor, texture, and consistency of any identification marks

2. Hardness Test: This is the force required to break a tablet in a diametric compression. Hardness of the tablet is determined by Hardness Tester.

3. Thickness and diameter: For tablets to be uniform among themselves and to be accepted by consumers, control over the physical characteristics of the tablets, such as size and thickness, is crucial. The die and punches used to make the tablets determine the diameter and punch sizes of the tablets. Vernier calliper is used to measure the thickness and diameter of tablet.

4. Friability: This test is performed to evaluate the ability of tablets to withstand abrasion in packing, handling and transporting. Initial weight of 20 tablets is taken and these are placed in the friabilator, rotating at 25rpm for 4min. The difference in the weight is noted and expressed as percentage. It should be preferably between 0.5 to 1.0%.

5. Average weight of tablet: It is desirable that all the tablets of a particular batch should be uniform in weight. If any weight variation is there, that should fall within the prescribed limits as per IP/BP

6. Disintegration test: For most tablets the first important step toward solution is break down of tablet into smaller particles or granules, a process known as disintegration. This is one of the important quality control tests for disintegrating type tablets. Six tablets are tested for disintegration time using USP XXII apparatus. Disintegration type conventional release tablets are tested for disintegrating time.

7. Effervescence time: It refers to time taken by an effervescent tablet to completely disintegrate in water with release of carbon dioxide.

8. Antibacterial testing: Antibacterial activity against Streptococcus mutans bacteria by preparing the culture of mitis salivarius agar. The petri dish that contained selective medium

were previously prepared during sample collecting period by dissolving 90 g/L of agar in distilled water and add 20% of sucrose then mixture was placed in wet sterilizer at 110℃ temperature and pressure 15 psi for 15 min. then mixture is cooled.

Result and Discussion:

UV – Visible Spectroscopy: Determination of Maximum wavelength in methanol: The absorption maxima of Biomin F was found to be 210 nm in methanol.

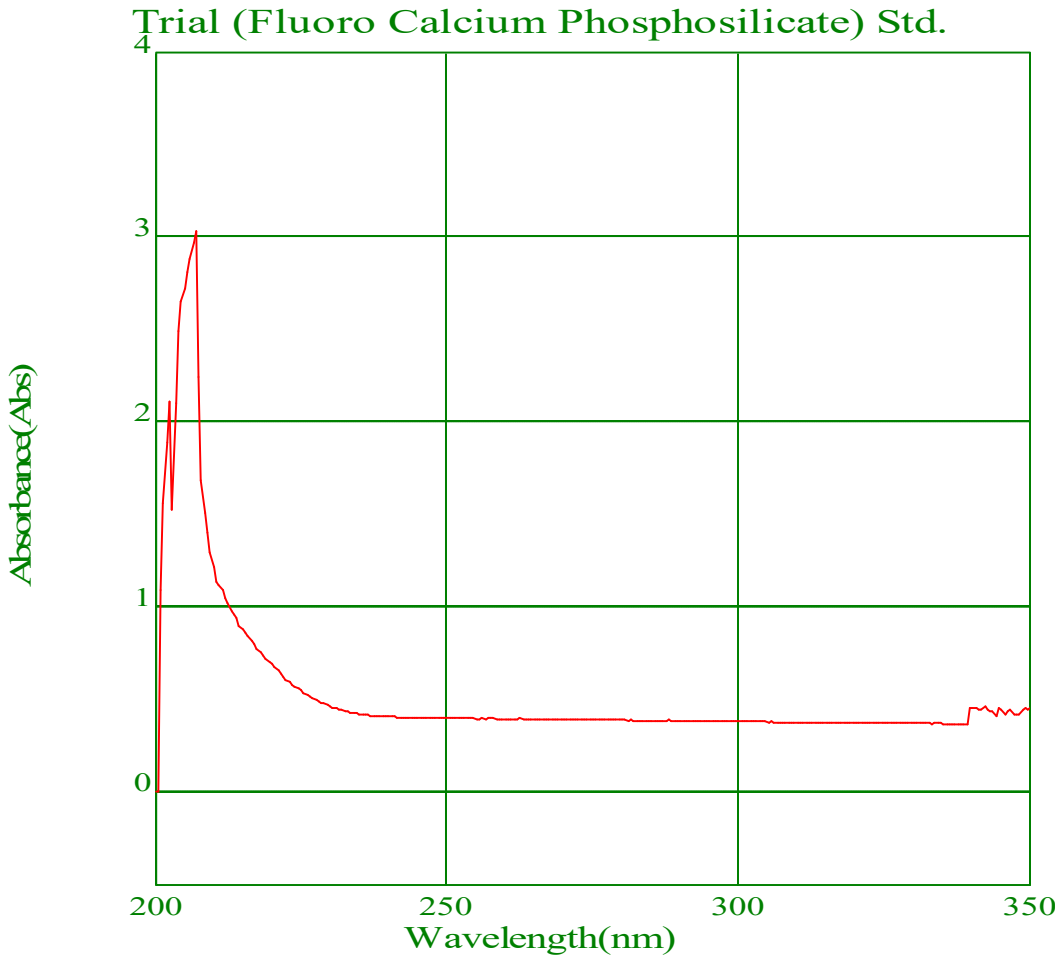

Fig. no. 1: Absorbance maxima of Biomin F

Preparation of standard calibration Curve: The sample of different concentration was analysed at 210 nm using UV spectrophotometer against methanol

Table No.3: Calibration table of Biomin F

Sr.no.	Concentration(µg/ml)	Absorbance (at 210nm)
1.	05 µg/ml	0.146
2.	10 µg/ml	0.301
3.	15 µg/ml	0.449
4.	20 µg/ml	0.599
5.	25 µg/ml	0.723
6.	30µg/ml	0.893

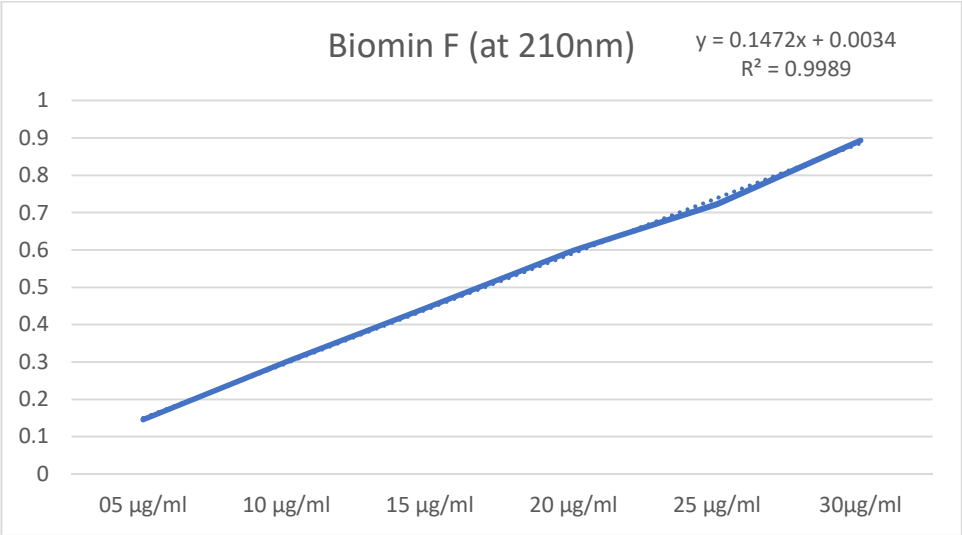

Figure No. 2: Calibration curve of Biomin F

Transmission Electron Microscopy:

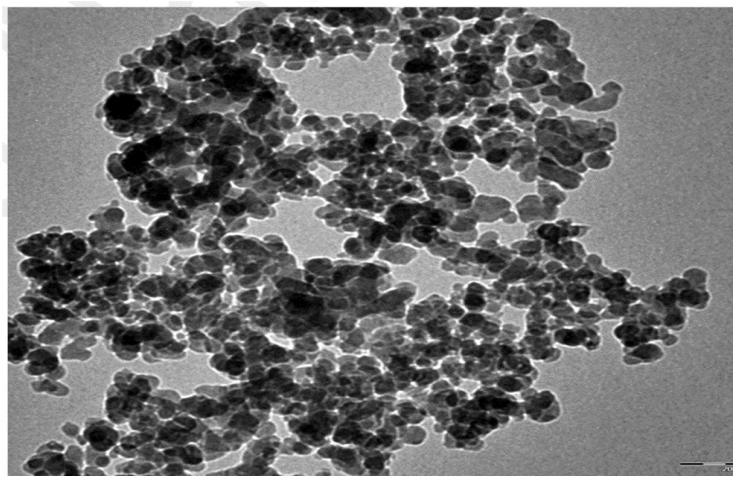

Figure No. 3: Transmission Electron Microscopy

X-ray Diffraction:

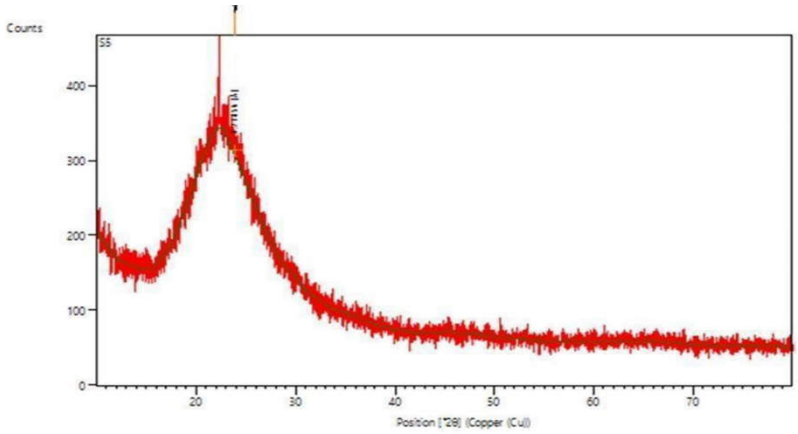

Figure No. 4: X-ray Diffraction

Scanning electron microscopy:

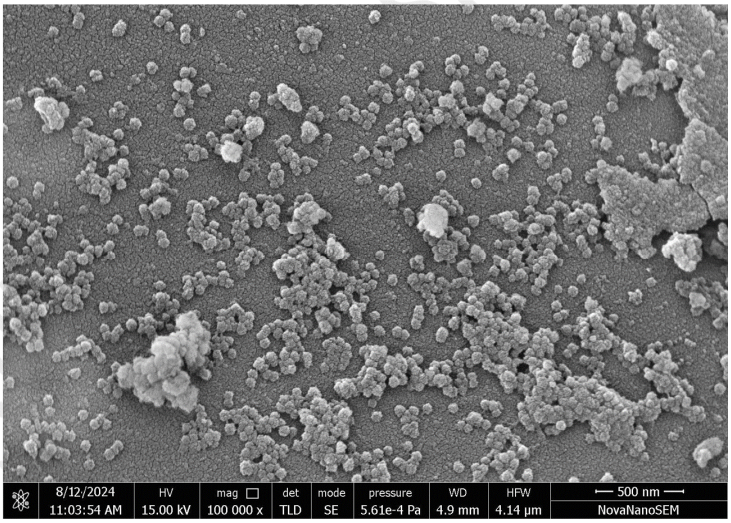

Figure No. 5: SEM

EDAX Analysis:

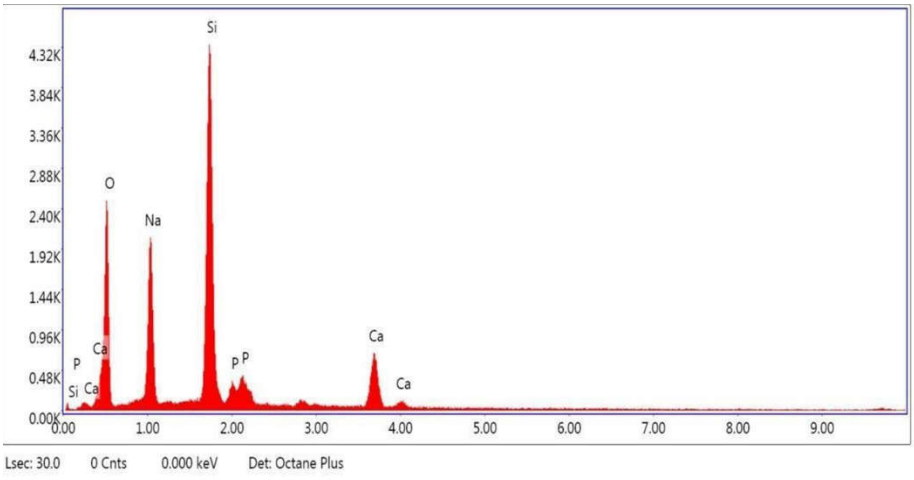

Figure No. 6: EDAX Analysis

Drug excipient compatibility study:

Table No. 4: Compatibility study

SR.NO	EXCIPIENTS	RATIO	DESCRIPTION	
			Initial	Final
1	API	1:1	White powder	White powder
2	API–Excipients	1:1	White powder	White powder

Pre-formulation study:

Table No. 5: Pre-formulation study

Sr.no.	Batch no.	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Compressibility index	Hausners ratio	Angle of repose
1.	F1	0.63	0.71	11.3	1.13	31.7
2.	F2	0.65	0.83	21.7	1.28	36.4
3.	F3	0.78	0.96	18.9	1.23	42.1
4.	F4	0.75	0.97	22.7	1.29	46.7

Physicochemical evaluation:

Table No. 6: Physicochemical Parameter

Sr. no.	Batch no.	Physical appearance	Average Weight (mg)	Thickness (mm)	Diameter (mm)	Hardness (kg/cm^2)	Disintegration time/ Effervescence time
1.	F1	White colour, biconvex, having break line on one side and plain on other side of each tablet	250	3.1	7.0	5	42 sec

2.	F2	White colour, biconvex, having break line on one side and plain on other side of each tablet	251	3.11	7.02	8	01 min 32 sec
3.	F3	White colour, biconvex, having break line on one side and plain on other side of each tablet	250	3.11	7.01	3	51 sec
4.	F4	Pale yellow colour, biconvex, having break line on one side and plain on other side of each tablet	252	3.1	7.01	4	31 sec

Table No.7: Friability

Batch	Initial weight (g)	Final weight (g)	Friability (%)
F1	6.50	6.491	0.14%
F2	6.50	6.477	0.35%
F3	6.50	6.489	0.17%
F4	6.50	6.461	0.60%

Antimicrobial testing:

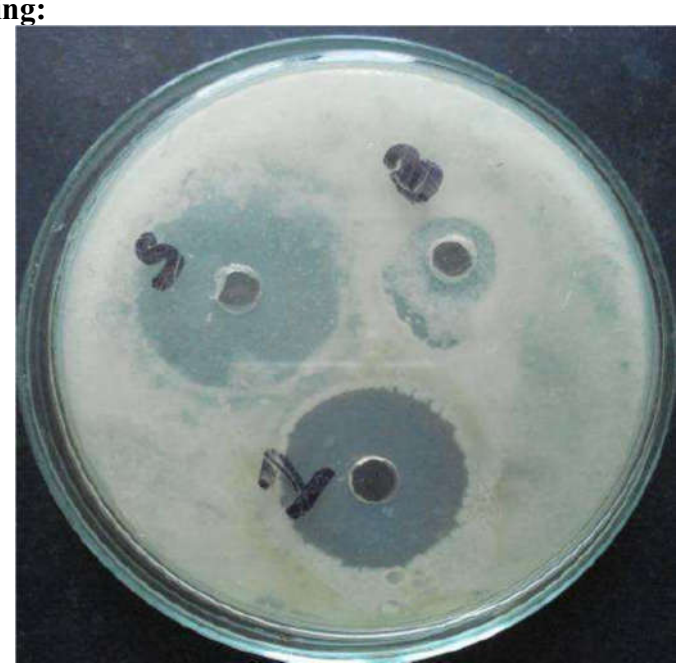

Figure No. 7: Zone of inhibition of Biomin F

Table No. 8: Antibacterial activity of sample (F1, F2, F3) against Streptococcus mutans

Sr. no	Sample	Batch no.	Day1 Zone in Diameter (mm)	Day2 Zone in Diameter (mm)	Day3 Zone in Diameter (mm)	Day4 Zone in Diameter (mm)
1	Sample: Biomin F tooth tablet	F1	1.6	2	2.9	3.1
2	Sample: Biomin F tooth tablet	F2	1.6	2.1	2.8	3.2
3	Sample: Biomin F tooth tablet	F3	0.4	0.7	1.1	1.5

Conclusion: The given sample F1 used for the antibacterial activity by using bacterial strain Streptococcus mutans showed better activity than F2 and F3.

Conclusion: The study was undertaken with an aim to formulate effervescent tooth tablet of drug Biomin F. Effervescent tooth tablets were prepared by direct compression methods to replace the conventional toothpaste of Biomin F in treatment of dental problems. The results obtained at each stage of formulation were utilized and the best formulations selected. During compression F3 and F4 Tablets showed the tablet defects i.e. sticking and picking. After performing the required studies, citric acid, sodium bicarbonate and sweeteners were selected. Pre and post-compression tests were conducted on the prepared tablets. Peppermint and xylitol flavors were more effective in masking the bitter taste of Biomin f. Finally, the F1 formulation of 250 mg tablets were selected as the best formulation because of their physicochemical characteristics and meet all the specified limits. It is significant that direct compression method resulted in better tablets.

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