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Development and Clinical Assessment of Oral Dispersible Tablet of *Cordia Dicotoma* and *Salvia Hispanica* Mucilage for the Management of Stomatitis

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Abstract

The main objective was to formulate and clinical assessment of oral dispersible tablet comprising mucilage of *Cordia dicotoma* and *Salvia hispaica* in the management of stomatitis. The mucilage formed from macerating *Cordia dicotoma* fruits with solvent water and 1% HCl, *Salvia hispaica* were extracted using a 1:40 water ratio, stirred for two hours, then centrifuged to extract the mucilage. Pre-formulation and post-compressional studies were conducted for all the oral dispersible tablet formulations. A clinical study was conducted using the optimized formulation and evaluated for the clinical parameters such as red patch, blisters, swelling, pain and burning sensation for 14 days and grading of improvement for stomatitis was given by the subjects before and after treatment. When oral dispersible tablets were made with different amounts of mucilage, they dissolved quickly and took less time to release ascorbic acid hence tablet containing 150 mg of *Cordia dicotoma*, 100 mg of *Salvia hispaica* and 20 mg of red rock sugar was selected for a clinical investigation. Clinical parameters indicated the improvement of 68.54% for red patch, 70.07% for blisters, 68.86% for swelling, 67.49% for pain and 68.27% for burning sensation. Based on above clinical parameters developed formulation can be used for the management of stomatitis.

Keywords

Cordia dicotoma, *Salvia hispanica*, Ascorbic acid, Stomatitis

Article history

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1. Introduction

Oral recurrent aphthous stomatitis (RAS), is the most prevalent form of ulcerative illness in the oral mucosa. Mostly affecting non keratinized oral mucosa, recurring, self-limiting ulcers are the hallmark manifestation of RAS. More than 80 percent of RAS instances are minor, which is characterized by small, circular, painful, superficial ulcers up to 1 cm in diameter, surrounded by an erythematous halo and coated with a yellow-grey membrane. Ulcers in major RAS are usually deeper and bigger than those in small RAS. Herpetiform ulcers are characterized by multiple recurring clusters of small ulcers (less than 4 mm in diameter) distributed throughout the oral mucosa. These ulcers have the potential to develop into more extensive ulcerations, RAS has been associated with various genetic, dietary, viral, and psychological factors [1].

Despite developments in drug delivery technology, the oral route remains popular due to exact dosing, low cost, non-invasiveness, and convenience of administration, resulting in high patient compliance. Solid dose forms can be difficult to swallow for certain patient groups, including youngsters, bedridden, uncooperative, nauseous, and those with limited water intake. Oral dispersible tablets (ODTs) have been created for a wide range of indications, from mental illness, where patient compliance is essential in treating long-term conditions like schizophrenia and depression, to migraines, where rapid-acting medication is essential [2].

The leaves, stems, and fruits of *Cordia dicotoma*, a member of the Boraginaceae family, are among the most medicinal plants in the world. *Cordia dicotoma* contains saponins, alkaloids, carbohydrates, tannins and glycosides. The fruits of *Cordia dicotoma* include proteins, Amino Acids, and flavonoids [3,4]. *Salvia hispanica* belonging to the family Lamiaceae is an herbaceous plant. It is mostly planted for its seeds. *Salvia hispanica* examined the chemical makeup of *Salvia hispaica* which contain high levels of lipids, carbohydrates, dietary fibres, proteins, vitamins, minerals and antioxidants [5].

Ascorbate (ascorbic acid, vitamin C) may generate or reduce the reactive oxygen species and furthermore, affect neutrophil apoptosis and bactericidal ability. It is possible that ascorbate controls the lifespan of neutrophils and induces the regression of minor recurrent aphthous stomatitis and periodontal health. The capacity of vitamin C to reduce outbreaks and pain levels in cases of minor-type Recurrent Aphthous Stomatitis [6].

The main objective was to develop oral dispersible tablet because they dissolve quickly and provide precised local relief at the site of ulcer using mucilage *Cordia dicotoma* and *Salvia hispanica*, mucilage will coat the wound of stomatitis and ascorbic acid helps in the management of stomatitis, where in application of gels they may wash away with saliva or food which requires frequent reapplication.

2. Materials and Methods

2.1 Materials

Codia dicotoma (authenticated by Dr. Avitha Marihal, PG Department of Botany, BVVS Akkamahadevi Women's Arts, Science and Commerce College, Bagalkote, Ref No. BVVS/AW/2023-24/03 dated 04/06/2024) matured fruits were collected from the fields of Ballatagi, Raichur district, *Salvia hispanica* seeds and red rock sugar (RRS) were obtained from the local herbal market of Bagalkot, Ascorbic acid, Talc, Magnesium Stearate and Crospovidone was procured from Fisher Scientific, Mumbai and stevia was procured from Organic India Pvt Ltd.

2.2 Methods

2.2.1 Procedure for Mucilage Extraction

Cordia dicotoma: Fruit of *Cordia dichotoma* washed and removed the outer coating, the pulp and 1000 g seed were macerated with 50 times their weight of water and left to stand for 24 hours.The extract was then squeezed through a muslin cloth. The filtered solution was precipitated using 1% Hydrochloric acid in a 1:3 proportion. The resulting mucilage was dried in hot air oven at 40°C for 24 hours. The dried mucilage was pulverized in mortar and pestle, passed through sieve number 85, and then dissolved in distilled water. Hydrochloric acid was used to precipitate the concentrated solution. After separation, the precipitate was dried at 60°C. The powdered dried mucilage was stored in a tightly sealed container as shown in Figure 1 [7].

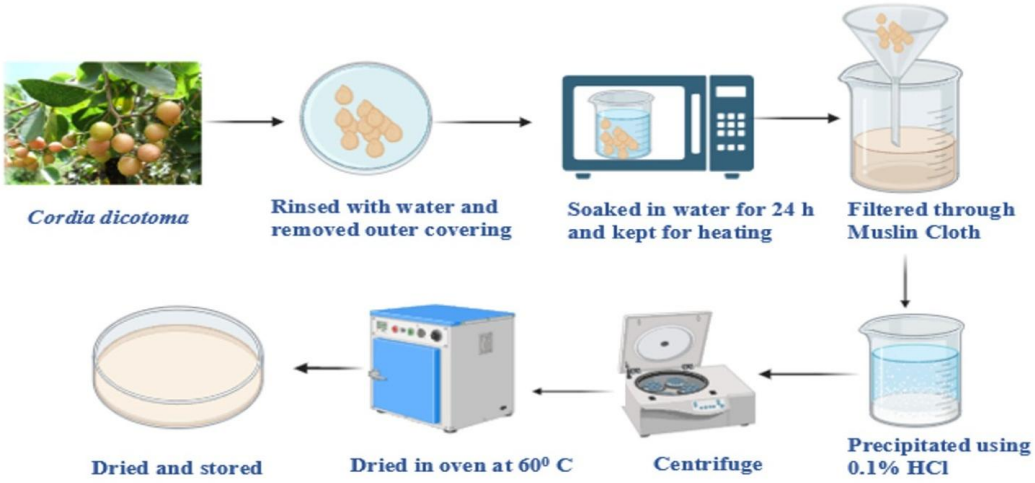

Figure 1. Schematic representation for extraction of *Cordia dicotoma*.

Salvia hispanica: *Salvia hispaica* seeds were taken and ground into powder. The powdered seeds were extracted with water at the ratio of 1:40 (Chia: water). The solution was stirred for 2 hours with maintaining Ph 7.8 by using 0.1 M NaOH buffer. Followed by centrifugation to the RPM of 12000 for 30 min at room temperature. Further, the mucilage settled in the middle layer was separated, collected and kept for drying at 40°C for 24 hours and passed through the sieve No. 85. Later the mucilage is stored in tightly closed container as shown in Figure 2 [8].

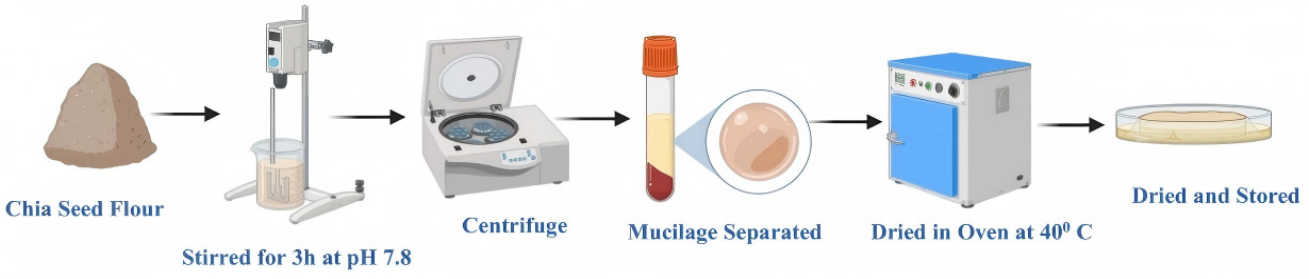

Figure 2. Schematic representation for extraction of *Salvia hispanica*.

2.2.2 Identification Test for Mucilage

FTIR Spectra: IR-Spectroscopy was used to check the compatibility of the ingredients present in the formulation by observing the shifts in the functional group vibrations. This analytical method was utilized to find any possible chemical interactions. The existence or absence of new peaks, peak shifts, or intensity changes in the infrared spectra of the pure components and their physical mixtures allowed for the evaluation of the physicochemical compatibility between the formulation's constituent parts.

Solubility Analysis: The solubility analysis included determining how soluble the mucilage was in the designated dissolving solvents like DMSO, ethanol, methanol, water and pH 6.8 phosphate buffer.

2.2.3 Phytochemical Tests of Mucilage

Molisch's Test: 100 mg of dry powder mucilage along with Molisch's reagent and concentrated H_2SO_4 forming confluence of two layers, violet-green coloration is observed and confirms presence of carbohydrate [9].

Iodine Test: 100 mg of dry powder mixed with 1 ml of 0.2 N iodine forming unobserved color which confirms the presence of polysaccharides.

Ruthenium Test: Examining a small amount of dried powder mounted on a glass with ruthenium red solution, forming pink color which confirms the presence of mucilage.

Fehling's Test: 100 mg of dry powder mucilage along with Fehling's reagent forming brownish-red precipitate which confirms the presence of reducing sugar.

Standard Calibration curve of Ascorbic Acid: Standard Curve was prepared in the conc range of 0.8-12 µg/ml (Beers Range). From the Stock I (1000 µg/ml) aliquots of 1, 1.5, 2, 2.5, 3, and 3.5 ml was taken and dilutions were made to obtain 10, 15, 20, 25, 30, and 35 µg/ml of Ascorbic Acid. The resulted solution was prepared in triplicates and absorbance was measured at 258 nm [10,11].

2.2.4 Preparation of Oral Dispersible Tablet

Using the direct compression method, oral dispersible tablets have been developed using super-disintegrants. As given in Table 1 the specified amount of *Cordia dichotoma* mucilage and *Salvia hispanica* mucilage are precisely weighed followed by excipients and passed through #85 mesh screened before combining. All the ingredients were taken in mortar ground in geometric pattern for 10 minutes. Later, the powder combination was compressed into tablets using a multi-station tablet compression machine with10mm flat surface punch. After adding magnesium stearate and talc in the needed proportions, to provide tablet hardness within the oral dispersible tablets pharmacopeial range, the compression force was modified [12].

Table 1. Formulation and composition of oral dispersible tablet.

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cordia Dichotoma	150	125	100	150	100	125	125	150	100
Salvia hispanica	80	100	100	100	60	80	60	60	80
AscorbicAcid	50	50	50	50	50	50	50	50	50
RRS	40	45	70	20	110	65	85	60	120
Stevia	30	30	30	30	30	30	30	30	30
Crosspovidone	143	143	143	143	143	143	143	143	143
Magnesium Stearate	4	4	4	4	4	4	4	4	4
Talc	3	3	3	3	3	3	3	3	3

3. Evaluation of Tablets

3.1 Pre-Compressional Parameters

The angle of repose (tan θ) was determined when the funnel tip contacted the top of the weighed tablet mixture. Free passage of the mixture through the funnel and to the top was permitted. After measuring the powder cone's height and radius, the angle of repose was calculated using the formula (1), where a and b represent the height and radius of the powder cone, respectively [13].

$$\tan\theta = a/b \quad (1)$$

Bulk Density: After precisely weighing the tablet mixture (a), it was placed in a graduated glass cylinder. After the powder was put into a graduated cylinder, the bed remained intact and undisturbed. Using the cylinder's graded markings, the volume was calculated in millilitres (b). The following formula (2) was used to calculate density, and the volume measured was the bulk volume [14].

$$\text{Bulk density} = a/b \quad (2)$$

Tapped Density: Tapped density was measured, the bulk volume of the same cylinder which was used for bulk density. A known weight (a) 10 mg of tablet mixture was tapped for 500 taps set up on the tap density device and after 500 taps the volume (b) occupied by the tablet mixture was noted. The formula (3) was used to calculate the tapped density [15].

$$\text{Tapped Density} = a/b \quad (3)$$

Carr’s index/Compressibility index: The compressibility index shows the blend's flow characteristics. While a high percentage of Carr's index denotes poor-flowing powder, a low percentage shows free-flowing powder. The Compressibility Index of tablet mixture was derived using the formula (4) [16].

$$\text{Carr’s index (\%)} = (T-B)/T\times 100 \quad (4)$$

Where, T is Tapped Density and B is bulk density

Hausner’s ratio: The ratio of tapped density (T) to bulk density (B), which is also correlated with inter particle friction, predicts the characteristics of powder flow. If the Hausner's ratio is low, the tablet mixture is easily flowable.

The equation (5) was used to calculate the result [17].

$$\text{Hausner’s Ratio} = T/B \quad (5)$$

3.2 Post Compressional Parameters

Appearance: Twenty tablets from each formulation were chosen at random for this test in order to examine the tablets physical characteristics, such as any discolorations or uneven surface.

Thickness: Determining the tablet's thickness is another crucial step. Since a filling machine is required to maintain a regular thickness, the thickness is helpful in replicating the appearance. The difference in thickness needs to be (±5) from the reference value.

Diameter: Vernier callipers were used to measure the tablets' diameter [18].

Hardness (Crushing Strength): The breaking force of tablet–the amount of force required to break them in a specific plan–is used to gauge their mechanical integrity. In order to exert sufficient stress to induce fracture, two platens are positioned between tablets, and one of them moves [19].

Friability: Gather a sample of an entire tablets weighing at least 650 mg, preferably 6.5 g. Sample 10 tablets if the total weight of the tablets exceeds 650 mg. Percentage friability was calculated using equation (6) [20].

$$\% \text{ Friability} = (Wt1 - Wt2)/Wt1 \times 100 \quad (6)$$

Wt1 = weight of tablets before friability testing.

Wt2 = weight of tablets after friability testing.

Weight Variation: Computed the mean weight of 20 randomly selected tablets from each batch of the formulation. Only two individual weights differ from the average weight by more than the percentage specified by the pharmacopoeia, and none by more than twice that amount [21].

In-vitro Disintegration Time: The disintegration apparatus composed of six glass tubes with a 10-mesh at the bottom, which are 7.75±0.25 cm long and have an internal diameter of 2.15 cm, according to USP. Six tubes were put in a 1litre vessel at 37±2°C to simulate a disintegration environment. The system cycles between 28 and 32 times per minute, moving 5 to 6 cm up and down. When moving up or down, tablets were placed no closer than 2.5 cm from the bottom of the beaker and 2.5 cm below the liquid's surface [22].

In-vitro dispersion time: Two tablets were inserted in a 100 ml beaker of pH 6.8 phosphate buffer solution at 37°C. The time necessary for tablet dispersion was noted.

In-vitro dissolution studies: Procedure: Using a USP dissolution equipment type II (Electro Lab, Mumbai, India) with a paddle stirrer at 50 rpm and 900 ml of pH 6.8 phosphate buffer at 37±0.1°C, tablet dissolution was investigated *in-vitro*. Each test involved one tablet, and at predefined intervals, 2 ml aliquots were taken out and replaced with an equivalent volume of fresh buffer. The removed aliquots were then tested for drug content using a spectrophotometer at λ_{max} 258 nm. The release of ascorbic acid was also calculated and expressed as a cumulative percentage of the drug released [23].

Wetting time: In a glass Petri dish, it partially filled with water was used to hold a tablet on top of a band of filter paper that was resting on a glass slide. Water was absorbed through the bottom surface of the tablet, and wetting time was measured by measuring how long it take for water to reach the centre of the tablet on the upper surface [24].

Water absorption ratio: A small Petri dish containing six milliliters of water was filled with a piece of tissue paper that has been folded twice. The amount of time it takes to completely moisten a tablet was measured. Next, the moist tablet was weighed. Using the formula (7), the water absorption ratio R was calculated [25].

$$R = 100 \times (Xa - Xb)/Xb \quad (7)$$

4. Single Arm Open Label Clinical Study

4.1 Study Criteria

Study population for Clinical study was selected with the age ranged in between 25 to 60 years because healing capacities and immune responses, which could affect the study's outcome. Healing period of at least five days and a history of RAS for at least three months which ensures that participants experience a typical healing time for their condition having confirmed pattern of RAS, ensuring that short-term or incidental cases were excluded. Exclusion criteria for the study were the population who may introduce confounding variables in the study. Hence the women who are pregnant/planning of pregnancy and lactating because during pregnancy there will be hormonal changes which can alter the oral health and immune response. Population of RAS history with chronic alcohol consumption were also excluded which had a risk factor of deficiencies in vitamins and minerals (iron, vitamin B12, folic acid) can contribute to RAS and xerostomia [26,27].

4.2 Study Procedure

An observational study of recurrent stomatitis activity for an oral dispersible tablet containing *Cordia dicotoma* and *Salvia hispanica* mucilage was conducted over a 14 days period at B.V.V.S Ayurveda Medical College and Hospital, Bagalkote, with prior approval from the Institutional Ethics Committee (Reference No. AMVB-23-24/470) on Human Subject data collected and documented.

The data was collected according to criteria. Study participants were instructed to receive Oral dispersible tablets containing mucilage of 500 mg/day after the food.For 14 days, all doses were taken orally once a day after meals. Subjects' analysis of stomatitis was made by various criteria like Red Patch, Blisters, Swelling, Pain and Burning

Sensation. The assessment score given by the subjects was calculated by adding the four scores for each of the following criteria: No (0), Slight (1), Moderate (2), and Severe/Continuous (3). The current study's data was gathered from treatment charts and subject case notes of 30 subjects. The student paired "t" test was used to statistically process the final results that were obtained by comparing the scores given by the participants of before treatment and after the treatment.

5. Result and Discussion

Cordia dicotma and *Salvia hispanica* mucilage containing Oral Dispersible Tablets were developed and evaluated for their ability to reduce stomatitis. Tablets were prepared through direct compression method by varying the concentration of mucilages.

5.1 Identification Tests for Mucilage

5.1.1 FTIR Studies

To examine how the extracted product interacts with other excipients. The FTIR spectra of formulation showed a peak at 1024 cm^{-1} which is assigned as C-OH aldehyde compounds, a peak at 1112 cm^{-1} which is due to stretching of carbonyl ketones. The peak at 1162 cm^{-1} is assumed to be C-O-C stretching of ethers, the peak at 1733 cm^{-1} is due to stretching of esters, peaks at 1645 cm^{-1} and 2916 cm^{-1} are found to –CH alkenes, peak at 3403 cm^{-1} is found to be -OH alcohol.

Based on correlation of the peak results between the mucilage and formulation spectra and the data interpretation (Figure 3A-D), it can be claimed that there was no interaction between the mucilages and the other excipients because there was no change or shift in the bands.

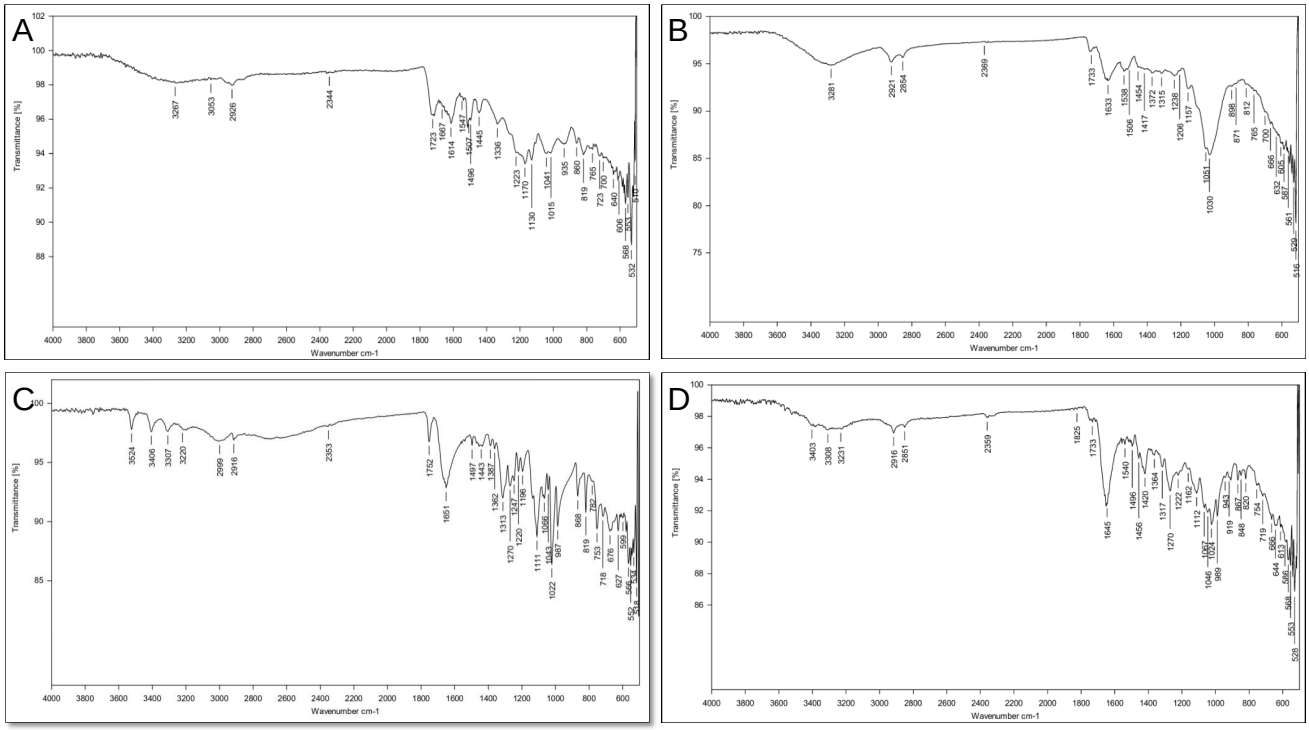

Figure 3. FTIR spectras. (A) *Cordia Dichotoma*. (B) *Salvia hispanica.* (C) Ascorbic Acid. (D) Formulation.

5.1.2 Solubility Analysis

Solubility analysis of mucilage was carried out to confirm the mucilage remained insoluble at oral pH, it was observed that mucilage was partially soluble in DMSO, slightly soluble in ethanol, methanol, insoluble in water and pH 6.8 phosphate buffer. which in turn is a required to covers the stomatitis and forms physical barrier and helps in the healing of sores associated with stomatitis.

5.1.3 Phytochemical Tests of Mucilage

Mucilage was subjected for phytochemical investigation, which revealed the presence of carbohydrate, reducing sugar and absence of polysaccharides. Ruthenium test showed pink colour which confirms the presence of mucilage [7,8].

5.2 Pre-formulation Studies

As powder blend in all batches have the angle of repose value less than 45°.69', all batches show fair flow property. The percentage compressibility is found to be less than 34.23, which indicates passable flowability. As the hausner's ratio value was found to be less than 0.133 which indicates passable flowability. Every formulation was assessed for its thickness, diameter, hardness, percentage of friability, wetting time, water absorption ratio, in vitro drug release studies, in vitro dispersion time, and in vitro disintegration time.

All formulas' tablet diameters and thicknesses ranged from 10.39 to 10.49 mm and 6.39 to 6.49 mm, respectively. A range of 1.5 to 2.5 kg/cm^2 was the tablet's hardness. The range of pill weight variation was determined to be between 500.4 and 502.4. The % Friability for all the formulations was found to be within 0.159 to 0.477. It was discovered that the water absorption ratio for each batch fell between 50±1.2% and 61.84±1.34% as shown in Figure 4. The *in-vitro* dispersion, wetting, and disintegration times for each formulation ranged from 14±1 to 27±2 seconds as shown in Figure 5, respectively. It was observed that as the concentration of *Cardio dichotoma* and *Salvia hispanica* mucilage increased there was decrease in disintegration time of the tablet [28]. All the formulations exhibited good percentage drug release. Tablet prepared with maximum concentration of mucilage's showed maximum % drug release. The rate of ascorbic acid release decreases with decrease in the concentartion of both the mucilage's in the formulation, whereas crossprovidone helped in the dispersion of tablet at pH 6.8 buffer which mimiced the oral pH which in turn help the mucilage in the formulation to get released and may coat the ulcer in the mouth, rock salt and stevia acted as sweetning agent for better palatbility to the patients and ascorbic acid helps in healing stomatitis.

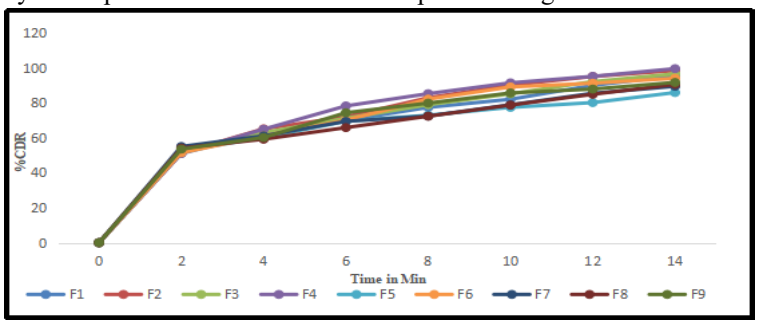

Figure 4. Percentage drug release studies of F1to F9. (n=3).

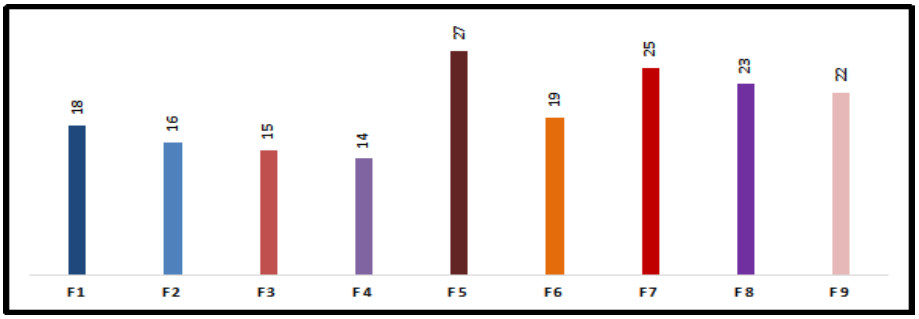

Figure 5. Disintegration time of F1 to F9 in seconds. (n=3).

5.3 Clinical Assesement Results

In the present work, extraction of mucilage from *Cordia dicotoma* and *Salvia hispanica* for the formulation of ODTs and its potential for anti-inflammatory, anti-ulcerative, wound healing properties. Where ascorbic acid in the tablet acted as antioxidant and marker compound to understand the dispersion pattern of mucilage. The formulated tablet of maximum concentration of *Cordia dicotoma* and *Salvia hispanica* mucilage's administered to the subjects in the age group of 25 to 60 years for 14 days in B.V.V.S Ayurveda College and Hospital Bagalkote.

The 33 patients diagnosed for Recurrent Aphthous Stomatitis were included in the study, after obtaining the written consent, the patients were treated and 3 patients did not show up for follow up treatment. The patients were instructed to administer a tablet once a day after meal. Further, distribution of patients was made based on the scores of Red Patch, Blisters, Swelling, Pain and Burning sensation for observational indication of improvement with statistical analysis. Shah D *et al* reported a notable decrease in the ulcer index was observed in Wistar rats treated with the water extract compared to those receiving the methanolic extract. The results were also evaluated against the standard drug, ranitidine (50 mg/kg). The water extract demonstrated a significant anti-ulcer effect in both the aspirin-induced gastric ulcer model and the pylorus ligation model [29]. Pintapagung T *et al.* reported antioxidants and fatty acids included in chia seed extract have positive effects on wound healing [30].

5.3.1 Red Patch

The impact of the tablet on the Red Patch was reduced to 68.5% as shown in Figure 6, participants was determined by the formulation's progress; The Statistical analysis revealed that the mean value of red patch which was 2.00 at the baseline has reduced to 0.63 depicated in Figure 7A. This decrease in red patch is statistically significant compared to baseline.

5.3.2 Blisters

According to the progression of the formulation that was administered, the tablet's effect of blisters in the subjects was reduced to 70.07% as shown in Figure 6. The mean value of blisters, which was 1.57 at baseline, has decreased to 0.47 (70.07%), according to the statistical analysis as shown in Figure 7B. When compared to the baseline, this drop in blisters is statistically significant.

5.3.3 Swelling

The impact of tablets on swollen participants was determined by the formulation's progress and was reduced to 68.53% as shown in Figure 6. According to the statistical analysis, the baseline mean value of swelling, which was 1.83, has decreased to 0.57 as shown in Figure 7C. When compared to the baseline, this drop in swelling is statistically significant.

5.3.4 Pain

The effect of the tablet on the pain-suffering participants was determined by the progression of the formulation that was delivered and was reduced to 67.49% as shown in Figure 6. According to the statistical study as depicated in Figure 7D, the baseline mean value of pain, which was 1.63, has decreased to 0.53. When compared to the baseline, this pain reduction is statistically significant. Patients with oral mucosal lesions experienced less discomfort and inflammation because of ascorbic acid and mucilage [31].

5.3.5 Burning Sensation

The impact of the tablet on the subjects experiencing burning sensation was determined by the progression of the formulation that was provided and was reduced to 68.27% as shown in Figure 6. According to the statistical analysis, the mean Burning Sensation value, which was 1.67 at baseline, has decreased to 0.53 as shown in Figure 7E. Comparing this drop in burning sensation to the baseline, it is statistically significant.

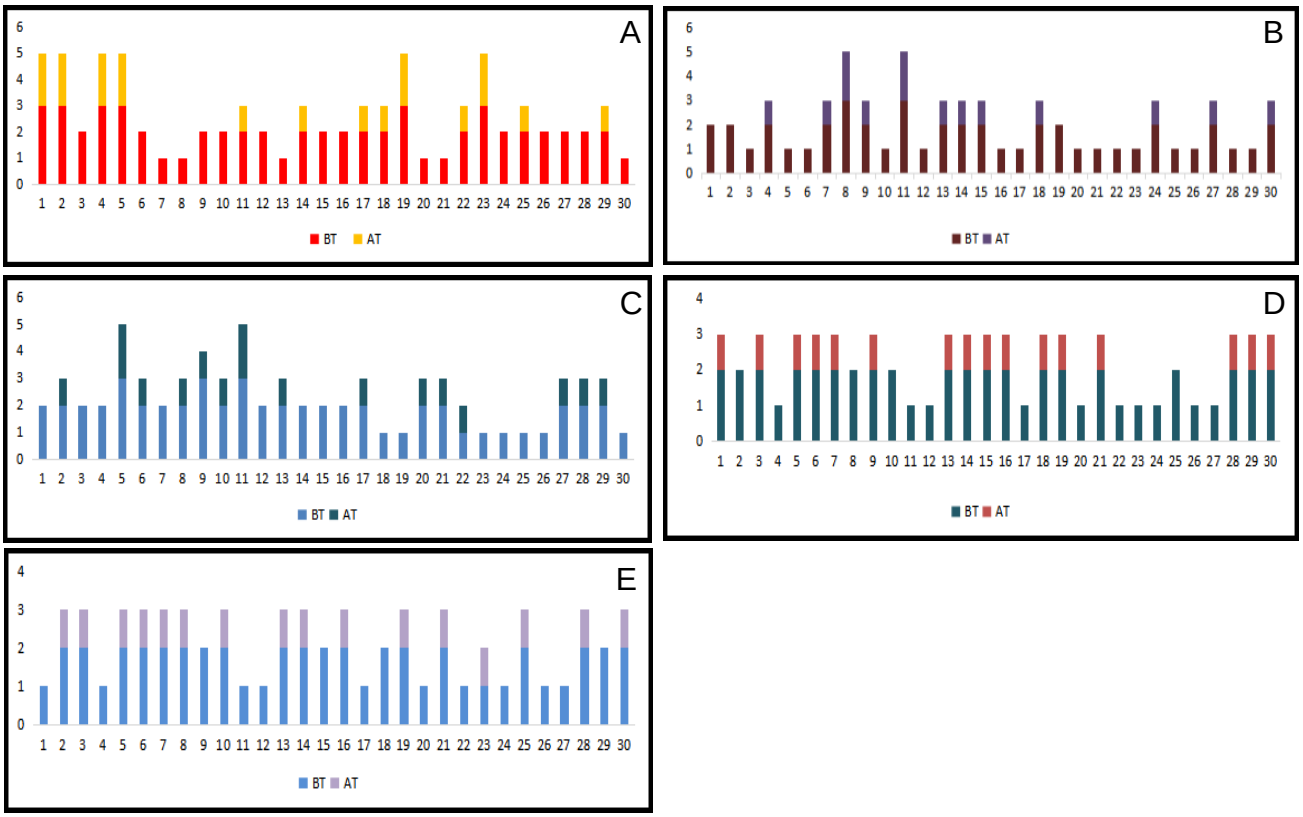

Figure 6. Effect of tablets on subjects after treatment (AT). (n=30). (A) Red patch. (B) Blisters. (C) Pain. (D) Swelling. (E) Burning Sensation.

5.3.6 Statistical Analysis: For paired 't' test

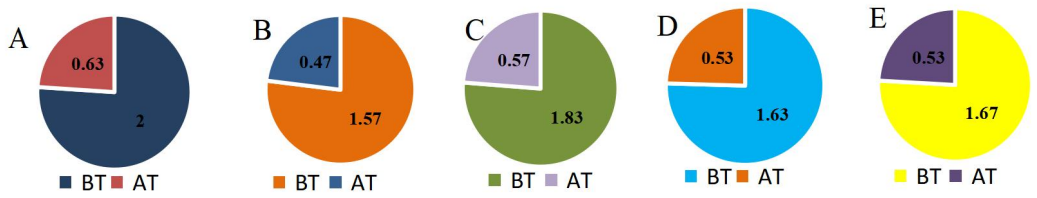

Figure 7. Improvement of parameters within subjects. (n=30). (A) Red Patch. (B) Blisters. (C) Swelling. (D) Pain. (E) Burning Sensation.

6. Conclusion

All formulations demonstrated fair to passable flow properties and consistent tablet characteristics, including optimal thickness, hardness, and friability. An increase in the concentration of Cardio dichotoma and Salvia hispanica mucilage significantly reduced the disintegration time and enhanced drug release. The use of crosspovid one facilitated faster dispersion at oral pH, supporting mucilage coating on stomatitis ulcers. The formulated tablet significantly reduced symptoms of red patches, blisters, swelling, pain, and burning sensation, with reductions ranging from 67% to 70%. The presence of ascorbic acid and mucilage contributed to rapid healing, reduced inflammation, and improved patient comfort. Overall, the developed tablets showed promising potential for effective stomatitis management with improved patient compliance.

Acknowledgement

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Conflict of Interest

"The authors declare that there is no real, potential, or perceived conflict of interest for this article".

Ethics Committee Approval

Reference no: AMVB-23-24/470 from Institutional Ethics Committee (IEC for research on human subjects) of BVVS Ayurved Medical College & Hospital, Bagalkot. On July 31st 2023.

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