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Original Article

Development and Assessment of Mucoadhesive Buccal Tablets Containing Dapsone: A Pharmaceutical Innovation

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ABSTRACT

Objectives: This research involved developing buccal tablets with the drug Dapsone, using varying amounts of three substances: Carbopol 934, Hydroxypropyl Methylcellulose, and Sodium Carboxymethyl Cellulose. **Materials and Methods:** Twelve different tablet formulations were produced using the direct compression technique. These tablets were tested for various physical and chemical attributes, such as hardness, size, weight consistency, drug concentration, tendency to crumble, absorbency, surface acidity, and adhesive strength. The dissolution of the tablets was tested over 12 hr using a method from the Indian Pharmacopeia 2018, involving a rotating paddle in a pH 6.8 buffer. **Results:** The study found that the tablets met Pharmacopeia's standards in terms of weight, hardness, friability, diameter, thickness, and drug concentration. The swelling index varied from 112.93% to 455.12%, and the surface pH was stable between 6.72 and 6.96. Adhesive strength differed based on the concentration of carbopol 934. There was a wide range in the drug release rates among the different batches, with the highest being 99.66% and the lowest 45.22%. Only one batch achieved an effective and sustained release of 88.4%, with an ideal swelling index and adhesive strength. Fourier Transform Infrared Spectroscopy showed no interaction between the drug and the other tablet ingredients. **Conclusion:** The study concluded that it's possible to create effective Dapsone buccal tablets, and their characteristics are largely determined by the polymers used.

Keywords: Dapsone, Swelling index Mucoadhesion, Buccal tablets.

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INTRODUCTION

The oral route is widely preferred for drug delivery due to its ease of use, precise dosing, and patient convenience, allowing for self-administration and a controlled dosing schedule. However, it presents challenges like the first-pass metabolism effect, breakdown by gastrointestinal enzymes, and delayed drug action. To address these issues, mucoadhesive and sublingual drug delivery methods have been proposed as more effective alternatives.[1-3]

Mucoadhesive dosage forms, specifically designed to stick to mucosal surfaces, offer enhanced drug retention at the target site and controlled drug release, leading to improved therapeutic effects. These dosage forms include adhesive patches, gels, tablets, films, and discs. They are particularly useful in areas lined with mucosal layers, like the gastrointestinal and urogenital tracts, ears, nasal passages, and airways. These mucosal layers vary in structure, ranging from a single-layered epithelial lining found in the gastrointestinal tract, bronchi, and intestines, to a multi-layered epithelial structure present in the esophagus, vagina, and cornea.[4-6]

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Among these sites, the buccal mucosa is notable for its high vascularization and direct connection to the jugular vein, bypassing the gastrointestinal and liver digestion. Buccal medication conveyance includes engrossing prescription through the buccal depression's coating. This method offers advantages like easy administration, rapid termination of effects in emergencies, and the ability to include enzyme inhibitors or permeation enhancers.[7,8]

Mucoadhesive polymers, which can be natural, semi-synthetic, or synthetic, become sticky upon hydration and can target drugs to specific body regions. When these mucoadhesive products contact the mucosal membrane, they swell and spread, creating a strong bond with the mucosa. The polymers are then activated by moisture, allowing for a slow and steady release of the drug.[6]

Dapsone is an antimicrobial agent primarily used to treat leprosy, dermatitis herpetiformis, and certain types of pneumonia. It is a sulfone with significant anti-inflammatory activity, making it a potential candidate for COX-2 inhibition.[9] As a BCS class II drug, it is poorly soluble in water but highly permeable. Despite its effectiveness, the conventional oral administration of Dapsone often leads to various side effects, including hemolytic anemia, methemoglobinemia, and gastrointestinal disturbances. Therefore, a sustained-release buccal tablet formulation could offer a more convenient and effective therapeutic alternative.[10,11] This research aimed to develop various batches of mucoadhesive tablets containing the drug Dapsone, utilizing polymers such as Carbopol 934, Hydroxypropyl Methylcellulose (HPMC), and Sodium Carboxymethyl Cellulose (SCMC). The project also included a thorough quality control assessment of these tablet formulations.

MATERIALS AND METHODS

Drug and chemicals

For this study, Dapsone with a high purity level of 99.96% and a minimal loss on drying at 0.34%, was kindly provided by NATCO Pharma. Carbopol 934 was procured from Himedia Research centres in India. The concentration likewise utilized Hydroxypropyl Methylcellulose (HPMC) and Sodium Carboxymethylcellulose (SCMC), obtained from Loba Chemie Pvt. Ltd., Mumbai. Extra substances like Magnesium stearate, Microcrystalline cellulose powder 200 (MCCP 200), and Powder were bought from Sigma-Aldrich, Inc., situated in St. Louis, MO, USA. Every one of the pre-owned materials, including synthetic substances and reagents, were of scientific grade quality.

Instruments

The study utilized several high-tech instruments, including a High-Performance Liquid Chromatography (HPLC) device from Shimadzu, Japan, and a FTIR Spectrophotometer by Perkin-Elmer, USA. For assessing tablet properties, a dissolution apparatus was used alongside a digital hardness tester from Electrolab, India. Tablet friability was evaluated using a tester from Toshiba, India. UV spectrophotometric analysis and precise measurements were conducted using equipment from Shimadzu, Japan. Water used in the experiments was purified using a system from H-Tech Instruments Co. Ltd., China. The tablets were compressed using a 10-station machine from karnavati Engineering, India.

Dapsone mucoadhesive tablets Formulation

The tablets mucoadhesive in this study were crafted using a modified version of an established method. The compression technique (direct) was employed to compress the tablets, with different proportions of various polymer grades used. Initially, all the powders were precisely weighed in their pure forms. Dapsone was first blended with CP (Carbopol 934), and separately, the other polymers were mixed with talc. Both mixtures were then sieved through a 40-mesh screen and mixed for 5 min. In a different step, aerosil and MCCP 200 were combined in another pouch and mixed for 2 min. This mixture was then incorporated with the previous blend and mixed for an additional 5 min. Towards the end of the process; magnesium stearate was added to the mix. Once all the ingredients were thoroughly combined, the combination turned into compressed into drugs the usage of a ten-station tablet punch, each tablet averaging 250 mg in weight. The study produced twelve distinct batches of tablets, labelled from A1 to A12. The specific composition of each batch was adapted from a prior study, with certain modifications as outlined in Table 1 of the reference.

Assessment of tablet properties

Assessment of tablet properties Quality control evaluations for every one of the bunches of mucoadhesive Dapsone tablets were conducted according to procedures specified in the Indian Pharmacopeia 2018.[12]

Weight variation

Twenty pills from every bunch had been weighed making use of an accuracy digital equilibrium to decide their common weight.

Friability

For the friability take a look at, a hard and fast of twenty drugs from each batch were weighed and located in a friability testing apparatus (Friabilator). After the tool completed 100 rotations, the tablets were removed, cleared of any dirt, and weighed again. The friability percent become then calculated the use of the unique components (Equation 1).

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100 \quad (1)$$

Hardness

The hardness of the pills ends up evaluated using a tablet hardness tester, in which twenty capsules from every batch were tested. The procedure involved placing each tablet between two

probes - one fixed and the other adjustable. Force was applied through the adjustable probe until the tablet broke. The amount of force necessary to fracture the tablet was noted and used as an indicator of the tablet's hardness.

Drug content

Drug content determination by HPLC chromatographic

A bioanalytical method using reverse phase High-Performance Liquid Chromatography (HPLC) was designed to assay the drug content in the new batches of tablets, with the method being refined for rat plasma. The chosen chromatographic conditions were based on the dapsone tablet assay from the Indian Pharmacopeia 2018. The setup included a UV-visible detector tuned to a wavelength of 263 nm and an autosampler programmed for 20 µL sample injections at a go with a flow rate of 1 mL/min. Data recording was managed by lab solution software specialized for database integration. Chromatographic separation was completed on a C18 Luna column, measuring 15 cm x 4.6 mm with a 5 µm particle size. The mobile phase was an isocratic mixture composed of 55% Acetate buffer and 45% Acetonitrile. This solvent system was allowed to run for 10 min, with the dapsone standard showing a retention time of approximately 7.5 min. To ensure the system's reliability, the standard solution was injected five times in succession, after which the average tailing factor, the average number of theoretical plates, and the (RSD) relative standard deviation of peak areas were calculated to assess performance. The mobile phase for the chromatographic analysis was composed of a solution with 55 volumes of Acetate buffer, which was prepared by mixing 8.2 mL of Hydrochloric acid with 1000 mL of water, joined with 45 volumes of acetonitrile.

HPLC Preparation, standard and sample solution

To lead the examination, the underlying step included making a standard stock arrangement of Dapsone at a convergence of 1 mg/mL. This fixation was acquired Dissolve 100 mg of Dapsone into 100 mL of High-Performance Liquid Chromatography (HPLC) grade acetonitrile. To guarantee the Dapsone was completely disintegrated, the arrangement went through sonication in an ultrasonic water shower. A volume of 1 mL from this stock arrangement was additionally weakened to 10 mL utilizing a blend made of 55 sections acetic acid derivation cradle and 45 sections acetonitrile, going for the gold focus for the assay. In setting up the example arrangement, twenty tablets from each category were pulverized into fine dust. One dose of this powder is equivalent to 100 mg of dapsone., which was estimated and added to a 100 mL volumetric flagon. Then, roughly 60 mL of acetonitrile filled the jar, and the combination was exposed to sonication for 30 min to advance total disintegration. A while later, the volume in the carafe was changed in accordance with 100 mL utilizing the versatile stage, and the arrangement was separated. This sifted test arrangement was then weakened to similar extent to the standard solution. Finally, before their presentation into the HPLC framework, both the norm and test arrangements were gone through 0.22 µm PTFE channels (given by Thermo Logical, Waltham, Mama, USA). The measure of each clump was precisely resolved utilizing these carefully pre-arranged arrangements.

Mucoadhesion test

The utilization of Porcine buccal mucosa crammed in as the trial version for assessing bio grip. Gathered promptly after death, the mucosa was shipped to the research facility in Tyrode association and stored up with at room temperature. The cement strength of the tablets was resolved utilizing three repeats, utilizing an exclusively changed balance and porcine buccal mucosa strips, which were flushed in Tyrode arrangement. This technique is point by point in Figure 1. The mucosa was managed to the essential size and washed again with Tyrode arrangement. During the investigation, a section of the mucosa was fixed on a glass vial utilizing an elastic band, uncovering a roundabout region with a breadth of 1 cm. The vial was then submerged in Tyrode arrangement at a reliable temperature of 37°C±2.0°C for 10 min. Consequently, this vial and subsequent one has been placed to

Table 1: The research included creating various formulations of Dapsone Mucoadhesive buccal tablets, each batch having its distinct composition.

Ingredients	Quantity expressed in milligrams (mg)											
	A-1	A-2	A-3	A-4	A-5	A-6	A-7	A-8	A-9	A-10	A-11	A-12
Dapsone	100	100	100	100	100	100	100	100	100	100	100	100
Carbopol 934	25	30	35	40	25	30	35	40	25	30	35	40
HPMC	60	55	50	45	-	-	-	-	30	27.5	25	22.5
SCMC	-	-	-	-	60	55	50	45	30	27.5	25	22.5
Magnesium stearate	5	5	5	5	5	5	5	5	5	5	5	5
MCCP 200	50	50	50	50	50	50	50	50	50	50	50	50
Talc	5	5	5	5	5	5	5	5	5	5	5	5
Aerosil	5	5	5	5	5	5	5	5	5	5	5	5
Grand total	250	250	250	250	250	250	250	250	250	250	250	250

a degree relating to the thickness of the tablet. The actual tablet was gotten to the base vial with twofold sided sticky tape, and the place of the vials was adapted to the tape to connect with the mucosa. A uniform power was applied to the top vial for two min, guaranteeing even adherence of the tablet to the mucosa. Following this, the vial was associated with an equilibrium. The load on the right dish of the equilibrium was steadily expanded by additions of 0.5 g until the place of separation of the vials, with the all-out weight required for separation being recorded as the attachment strength esteem.

Swelling test

For each lot, three separate tablets were selected and their initial weight (W1) was recorded. Each of these tablets was then individually placed in distinct Petri dishes containing 5 mL of phosphate buffer at a pH of 6.8. At destined intervals of 1, 2, 4, and 8 hr, the tablets. Were taken out of the Petri dishes. Excess moisture on the tablets was gently absorbed using filter paper. After this, the tablets, now swollen, were weighed again to obtain their final weight (W2). The degree of hydration for each tablet was determined using a specific formula, referred to as Equation 2.

$$\text{Swellining index} = (W2 - W1/W1\ X100) \ldots\ldots(2)$$

In vitro dissolution studies

The dissolution of the tablets *in vitro* becomes done in accordance with the approaches certain within the Indian Pharmacopoeia 2018. The rotating paddle approach changed into hired to estimate the discharge of the medicine from the tablets. In this analysis, six tablet (n=6) have been tested. The dissolution medium comported of 900 mL of phosphate buffer at a pH degree of 6.8. The check was performed at a stable temperature of 37°C±2.0°C and the paddle of the equipment rotated at a velocity of 50 revolutions in step with minute. Throughout the test duration, 5 mL samples have been extracted hourly, and an equivalent quantity of sparkling medium become reintroduced to keep the whole quantity unchanged. These samples were then prolonged to a 50 mL the usage of the buffer, passed through a filter, and subjected to analysis with an ultraviolet (UV) spectrophotometer at 263 nm. The drug release percent from the drugs turned into calculated the use of a popular drug calibration curve. For the calibration curve training, a number one answer of Dapsone was prepared in phosphate buffer (pH 6.8). This result changed into also adulterated in addition to attain a lot of attention. The absorbance ranges of these results have been measured at 263 nm the operation of a UV spectrophotometer. This calibration curve changed into eventually applied to check the odds of drug released from the drugs.

Compatibility study

In the comity study between the medicine and excipients, Fourier Transform Infrared (FTIR) spectroscopy using an FTIR spectrophotometer was employed. The spectral analysis spanned a wavelength range of 4000 to 400 cm^{-1}. The procedure involved evenly distributing a sample, which could be either the drug on its own or a mixture of the drug with its excipients, in potassium bromide. This mixture was then pressed into disc shapes via making use of a pressure of 5 heaps for 5 min using a hydraulic press. Once the pellet becomes fashioned, it was placed in the path of the spectrophotometer's light beam to capture the IR spectrum. This technique is essential for examining the compatibility between the drug and its excipients, as it allows for the detection of any potential interactions or alterations in the IR spectrum, as referenced in the study.

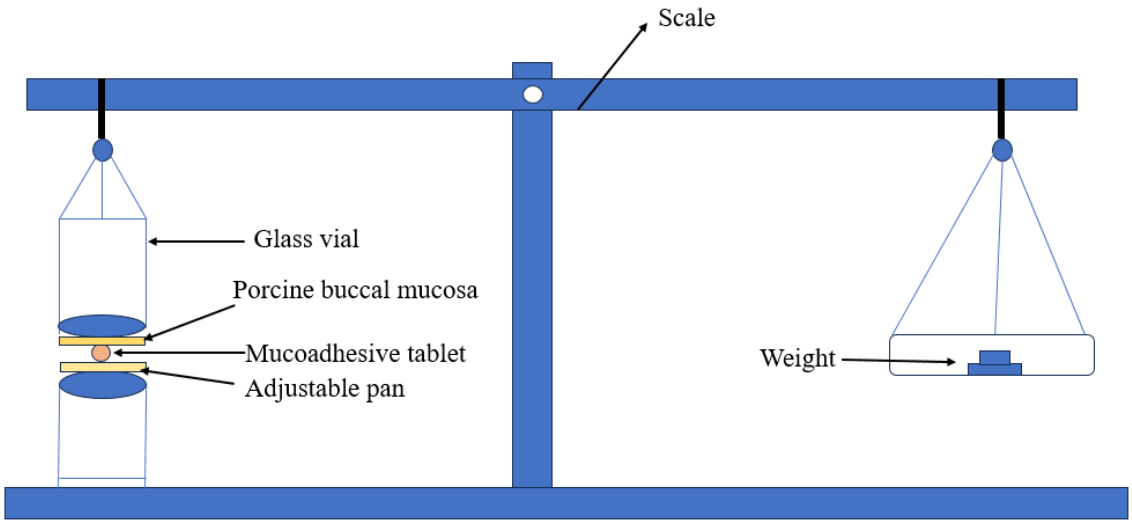

Figure 1: The fashionable layout of changed pan stability used for the dedication of mucoadhesion force of newly formulated tablets.

Surface pH studies

The pH measurement of three tablets (n=3) from each batch was conducted using a defined method. Each tablet was submerged in distilled water, which was pre-adjusted to a pH of 6.8. The tablets were then allowed to swell in this medium for a total of 2 hr. Following this period of swelling, the surface pH of each tablet was ascertained using a Digital pH meter that comes with an electrode attachment. This process is vital for determining the pH environment surrounding the tablets. Understanding the pH levels is critical for assessing the suitability and compatibility of the tablets with the biological system in which they are intended to be used, as outlined in the cited reference.[13]

Determination of release kinetics

The dissolution data for Dapsone released from the formulated batches were estimated using a range of fine models, including zero- order, first- order, Higuchi, Hixson Crowell, and Korsmeyer-Peppas models, to understand the medicine's release kinetics and medium. In the zero- order model, the medicine's release rate remains constant, not told by the medicine's attention. In discrepancy, the first-order model implies a attention-dependent release, which is represented by a logarithmic plot of the accretive chance of medicine remaining versus time. The Higuchi model is used to describe the medicine release from an undoable matrix, where the release is commensurable to the square root of time. This model is grounded on Fickian prolixity principles and is graphically depicted by conniving the accretive chance of medicine release against the square root of time. Meanwhile, the Hixson Crowell model accounts for medicine release patterns where changes in flyspeck or tablet face area and size do. To gauge the fit of the dissolution data for these models, the measure of determination (R2) is employed. This statistical measure assesses how well the experimental data aligns with the

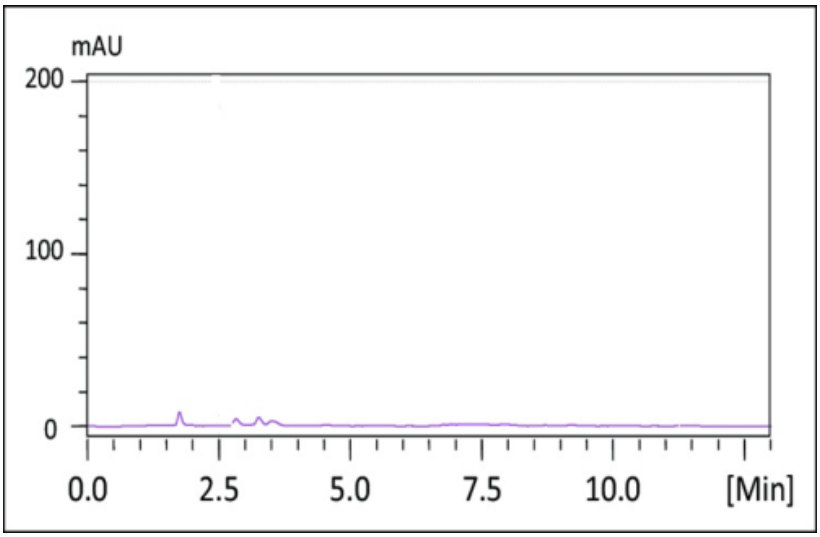

Figure 2: Chromatogram of blank of dapsone.

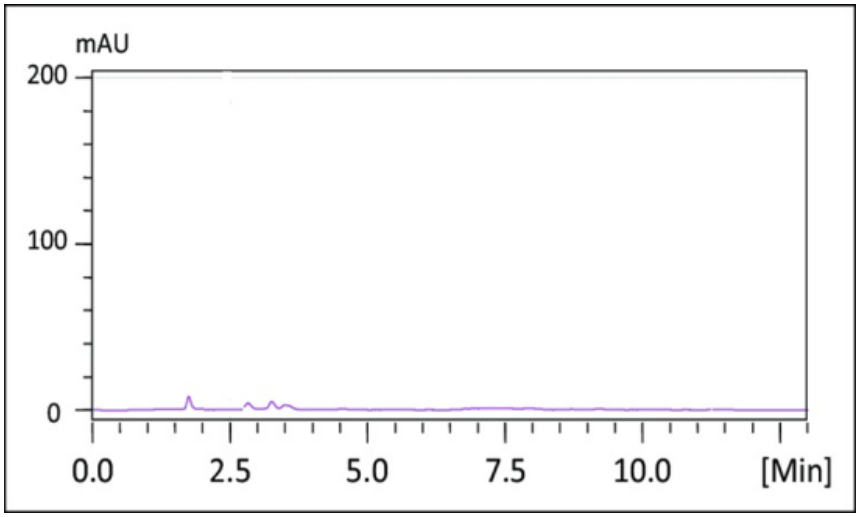

Figure 3: Chromatogram of placebo of dapsone.

retrogression models; a critical analysis points as indicated in the cited reference.[14-17]

Statistical analysis

The findings were expressed as the mean value with the standard deviation (Mean±SD). For statistical evaluation of the mucoadhesive strength among different batches, the study used the Tukey test in conjunction with one-way Analysis of Variance (ANOVA). In this analysis, a p-value less than 0.05 ($p < 0.05$) was deemed indicative of a statistically significant difference. The examination of drug release kinetics was conducted using DD Solver, a software specifically tailored for Analyzing drug dissolution data.[17]

RESULTS

Optimization of chromatographic conditions and calibration curve

The chromatographic evaluation of the recently developed Dapsone mucoadhesive tablets was performed in line with the protocols outlined in the Indian Pharmacopoeia (IP) 2018 specific to Dapsone tablets.[12] prior to the analysis, the system passed confirmation to confirm its delicacy and system felicity. The analysis time was extended to an aggregate of 10 twinkles. In the system felicity tests, critical parameters similar as the average trailing factor, average Number of Theoretical Plates (NTP), and the Relative Standard Deviation (RSD) of the peak area all complied with the respectable norms set by the IP 2018, with the trailing factor noted at 0.39.

Chromatograms of both the blank and placebo samples are shown in Figures 2 and 3, respectively. The chromatograms for the standard and test samples are depicted in Figures 4 and 5.

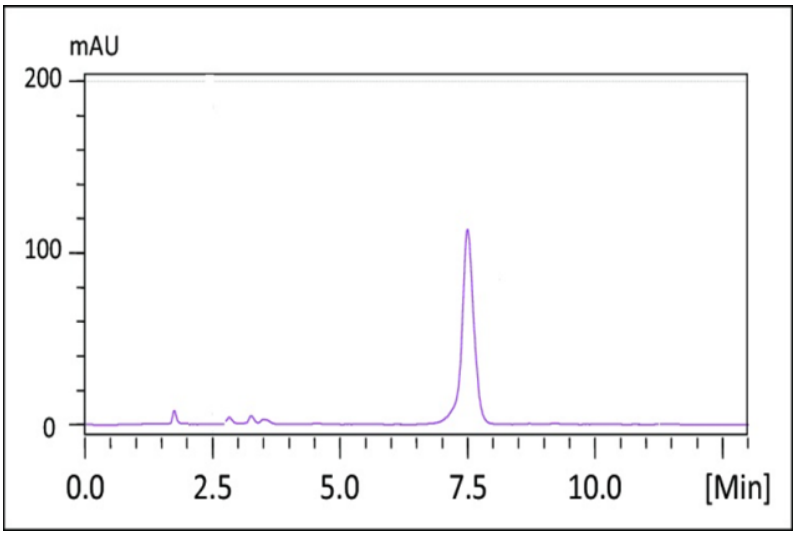

Figure 4: Chromatogram standard for dapsone.

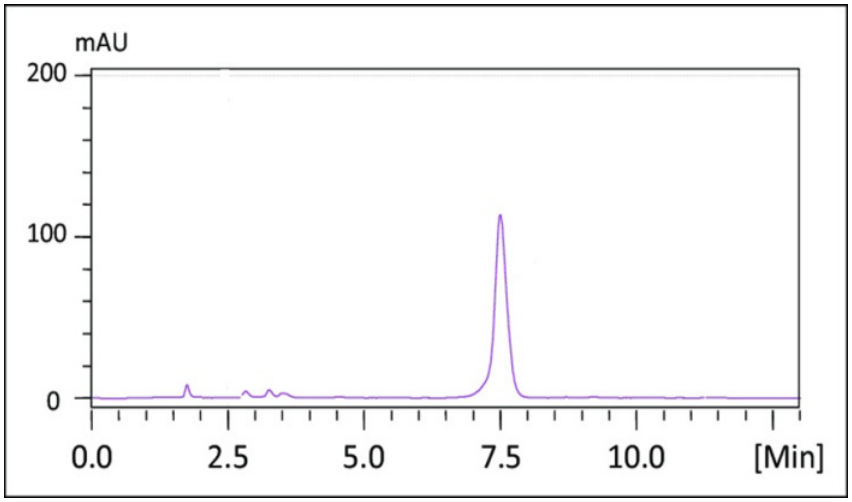

Figure 5: Chromatogram sample for dapsone.

It's important to note that the chromatograms for the blank and placebo (Figures 2 and 3) exhibited notable additional peaks. However, the chromatographic styles of all of the formulated batches (A1–A12) intently matched the usual drug's chromatogram (Figures 4 and 5).

DISCUSSION

Evaluation of tablet properties

Variations in weight, hardness, thickness, friability, diameter, and surface pH of the tablets

Table 2 offers the numerical statistics for numerous satisfactory manage parameters assessed across 12 unique batches. The weight variation evaluation found out that the pill weights ranged from 249.6±2.39 mg to 253.75±4.01 mg, fitting in the Indian Pharmacopeial requirements, which allow a deviation of 7.5% (231.25–268.75 mg). The thickness of the drugs remained steady throughout all batches, measuring between 3.8±0.00 mm and 4.05±0.05 mm. In terms of diameter, uniformity changed into observed at 9±00 mm in all batches. The friability of the drugs various between 0.04 to 0.2%, staying in the permissible range certain inside the Indian Pharmacopeia, that is underneath 1%. This shows that the capsules from all batches possessed adequate compactness and had been sufficiently proof against mechanical shocks and abrasion. The hardness test confirmed that the hardness values for unique batches were in the variety of 8.32±1.36 kg to 11.56±1.36 kg, demonstrating that the tablet hardness was within the pharmacopeial requirement of above 5 kg. Additionally, the surface pH for all batches changed into recorded among 6.72 to 6.96, aligning intently with impartial pH and falling in the appropriate buccal pH variety of 6.5 to 7.5.

Drug content

Table 2 indicates that the drug content across the various batches ranged from 97.67% to 103.03%. This variation demonstrates a high level of uniformity in the drug content among the different batches.

Mucoadhesive strength

The study conducted an *in vitro* examination of mucoadhesive strength, with the issues presented in Figure 6. The trial involved using a modified visage balance to measure the force necessary to separate the tablet from porcine buccal mucosa. It was observed that the mucoadhesive characteristics were significantly affected by the type and volume of bio-adhesive polymers included in the expression. The study specifically noted that the strength of mucoadhesion was specially told by the attention of Carbopol (CP) used. The weakest mucoadhesive strength was observed in batch A1, registering at31.57 g, which contained the lowest quantum of CP. Again, the strongest mucoadhesion was set up in batch A12, with a strength of 55.20 g, where the loftiest attention of CP was used compared to the other batches.

Swelling index

The assessment of the swelling properties for each batch involved measuring the swelling index at various intervals, specifically at 1, 2, 4, and 8 hr, with the results illustrated in Figure 7. All the formulations demonstrated a notable rise in their swelling index, which increased in proportion to the time elapsed, reaching the peak of swelling at 8 hr. Notably, throughout the duration of the study, there were no significant alterations in the morphological shape and form of the tablets. Batch A8, which included both Carbopol (CP) and Sodium Carboxymethyl Cellulose (SCMC), exhibited the highest swelling at 455.12%. In contrast, the lowest

Table 2: Quantitative information for various quality control assessment metrics of the newly developed 12 distinct batches.

Batch	Post-Compression Parameters (*n*=6)						
	Wt. Variation (mg)	Hardness (kg/cm²)	Friability (%)	Diameter (mm)	Thickness (mm)	Surface pH	Drug content (%)
A1	249.7±2.20	9.22±1.52	0.20	9	3.93±0.09	6.96±0.2	99.44±1.2
A2	249.6±2.39	8.32±1.36	0.14	9	4±0.00	6.72±0.4	97.67±0.56
A3	250.45±1.98	10.57±1.38	0.04	9	3.94±0.06	6.85±0.1	98.95±1.26
A4	250.75±1.97	11.14±1.07	0.07	9	4.03±0.04	6.88±0.25	98.00±1.36
A5	252.55±2.03	8.99±0.65	0.09	9	4.05±0.05	6.84±0.1	103.03±0.76
A6	251.75±1.91	9.41±0.81	0.05	9	4±0.00	6.86±0.2	101.16±2.01
A7	249.85±1.98	9.50±0.86	0.13	9	3.8±0.00	6.86±0.32	99.96±0.87
A8	249.7±2.55	11.25±1.34	0.11	9	3.9±0.00	6.80±0.15	98.90±1.13
A9	251.2±2.33	9.17±0.81	0.15	9	4±0.00	6.88±0.23	99.32±1.43
A10	253.75±4.01	10.29±0.56	0.15	9	4±0.00	6.95±0.32	99.86±0.32
A11	249.85±3.97	9.78±1.33	0.09	9	4±0.00	6.84±0.43	102.21±2.13
A12	251.35±3.71	11.56±1.36	0.07	9	4±0.00	6.82±0.19	101.53±1.76

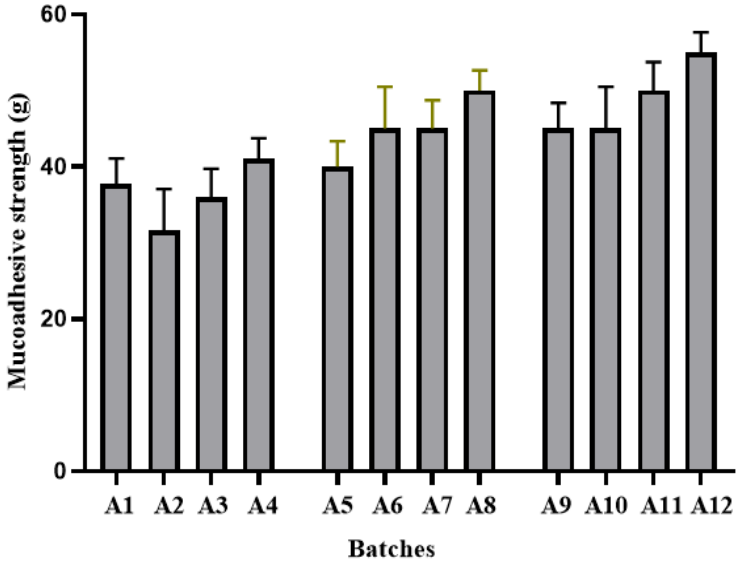

Figure 6: The adhesive strength of various batches, measured using a modified pan balance, shows a significant variation among the batches ($p<0.05$).

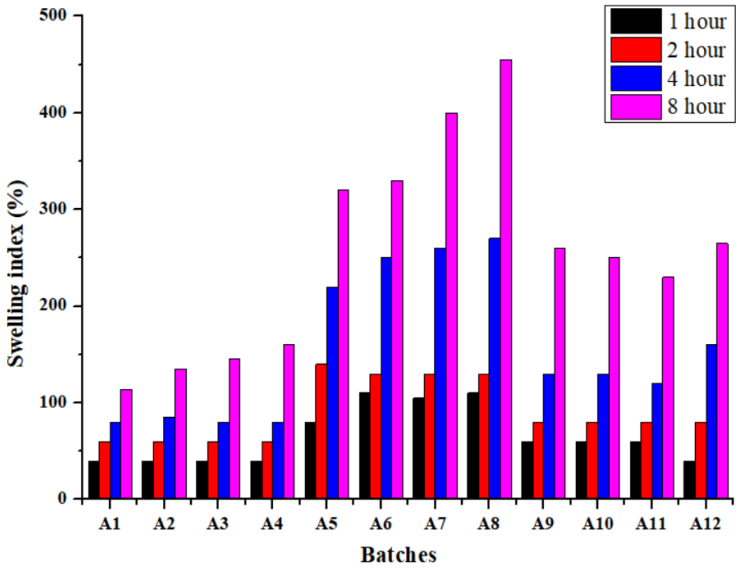

Figure 7: Comparative analysis of the swelling index for 12 batches of Dapsone mucoadhesive tablets over various time intervals.

swelling was observed in batch A1, with a rate of 114.16%, which was formulated with Hydroxypropyl Methylcellulose (HPMC) and CP.

In vitro dissolution studies

The *in vitro* dissolution study was conducted to investigate how the composition and proportion of polymers affect the drug release from mucoadhesive tablets, with findings presented in Figure 8. The study revealed a significant variation in drug release among the batches, with batch A12 showing the highest release at 99.66% and A3 the lowest at 45.22%.

For batches containing Carbopol (CP) and Hydroxypropyl Methylcellulose (HPMC) (A1–A4), the drug release rates were comparatively lower, even after 12 hr, being 88.40%, 75.21%, 45.22%, and 55.14% respectively. On the other hand, batches formulated with a combination of CP and Sodium Carboxymethyl Cellulose (SCMC) (A5–A8) demonstrated higher drug release

rates, with percentages of 99.12%, 99.32%, 99.45%, and 99.22%, respectively.

Additionally, batches that incorporated all three polymers (A9–A12) exhibited a similar pattern in drug release. Specifically, batches A9 and A10 showed drug release rates of 99.55% and 99.56%, respectively. Batch A11 achieved a release rate of 99.44%, and batch A12 reached 99.66% in a 12 hr period.

Determination of release kinetics

The outcomes from the *in vitro* disintegration studies were broke down utilizing different numerical models, and the connection coefficient (R^2) and example (n) values for models like zero-request, first-request, Higuchi, Hixson Crowell, and Korsmeyer-Peppas were introduced in Table 3. The review included plotting the logarithm of the combined level of medication held against time to comprehend the request for drug discharge for all bunches. The perception of higher R^2 values for the zero-request and first-request models suggested that batches A1 and A2 were more aligned with first-order kinetics, indicating a concentration-dependent release. In contrast, the release pattern for the other batches was more consistent with zero-order kinetics, where the release rate is constant. Table 3 confirmed

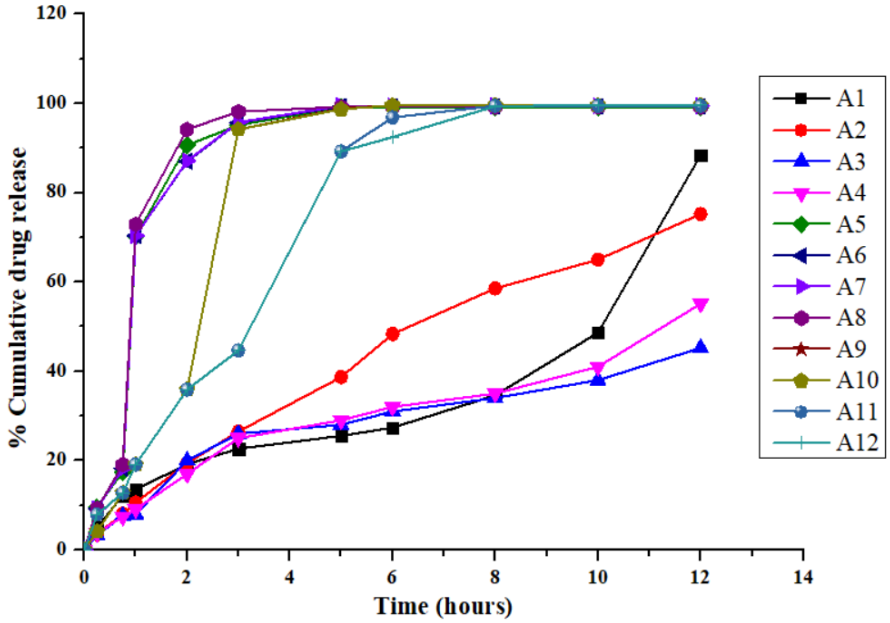

Figure 8: Comparative Dissolution profile of different batches of dapsone mucoadhesive tablets.

Table 3: Data on the release kinetics of all the batches.

Formulation Code	Kinetic Parameters											
	Zero order			First order			Higuchi			Korsmeyer-Peppas		
	a	b	r^2	a	b	r^2	a	b	r^2	a	b	r^2
A_1	3.204	5.454	0.930	2.039	0.051	0.812	6.852	18.950	0.879	1.088	0.597	0.959
A_2	4.699	6.294	0.991	2.005	0.048	0.997	9.020	23.051	0.987	1.028	0.805	0.999
A_3	6.862	3.451	0.947	1.972	0.020	0.966	1.688	13.214	0.986	0.970	0.670	0.981
A_4	5.499	4.039	0.974	1.983	0.025	0.978	3.658	14.989	0.983	0.984	0.677	0.993
A_5	40.236	6.999	0.717	1.620	0.189	0.873	16.21	30.543	0.851	1.538	0.577	0.858
A_6	39.873	7.053	0.724	1.636	0.203	0.881	15.82	30.689	0.857	1.536	0.580	0.863
A_7	39.899	7.065	0.725	1.637	0.213	0.884	15.81	30.738	0.857	1.537	0.580	0.863
A_8	41.862	6.858	0.698	1.528	0.188	0.840	17.81	30.215	0.837	1.548	0.571	0.851
A_9	20.984	9.005	0.838	1.879	0.241	0.913	4.521	36.270	0.918	1.263	0.862	0.957
A_{10}	21.049	9.010	0.836	1.834	0.244	0.878	4.499	36.305	0.917	1.263	0.862	0.957
A_{11}	14.691	9.232	0.918	2.097	0.228	0.966	8.614	35.594	0.962	1.306	0.744	0.982
A_{12}	14.438	9.206	0.923	2.149	0.239	0.977	8.657	35.411	0.966	1.305	0.742	0.983

that batches A1, A2, and A4 conformed to the Hixson-Crowell kinetic model, which means the drug release from these batches occurred through an erosion mechanism. The other batches, A3 and A5 to A12, were found to follow the Korsmeyer-Peppas models, suggesting that their drug release mechanisms were more complex, possibly involving more than one type of release process.

CONCLUSION

This research focused on developing and accessing mucoadhesive buccal tablets of Dapsone, designed for sustained drug release, to enhance patient adherence in managing various pain types. Out of 12 different formulations, batch A1 was notable for its consistent and efficient drug release, swelling behavior, and mucoadhesive properties, all in line with pharmacopeial standards. The study highlighted the significant role of Carbopol (CP) in enhancing mucoadhesive strength. It was found that by adjusting the ratio of CP and Sodium Carboxymethyl Cellulose (SCMC), the swelling characteristics of the tablets could be fine-tuned. However, high levels of SCMC were observed to cause a rapid release of the drug. In this context, Hydroxypropyl Methylcellulose (HPMC) proved crucial in moderating both swelling and drug release rates. The study underscores the need for comprehensive research into appropriate polymers and drug candidates. Additionally, the Dapsone mucoadhesive tablet formulation presents a promising alternative for bypassing the first-pass metabolism, thereby enhancing Dapsone's bioavailability through the mucosal route. This approach could potentially lead to improved patient compliance due to the prolonged drug release.

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ABBREVIATIONS

MAT: Muco Adhesive Tablet; **SCMC:** Sodium Carboxy Methyl Cellulose; **HPMC:** Hydroxy Propyl Methyl Cellulose; **CP:** Carbopol; **MCC:** Micro Crystalline Cellulose; **FTIR:** Fourier Transform Infra Red Spectroscopy; **HPLC:** High Performance Liquid Chromatography; **CF:** Compressionforce; **DSC:** Differential Scanning Calorimetry; **%CDR:** Percentage Cumulative Drug Release; **DT:** Disintegration Time; **DC:** Drug Content; **Opt:** Optimized; **DoE:** Design of Experiment.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

SUMMARY

This novel approach meticulously optimizes carbopol 934, HPMC, and SCMC for the development of Dapsone Buccal tablets, with a specific focus on mucoadhesion phenomenon. Furthermore, the study designates carbopol 934, HPMC as critical materials, underscoring their pivotal roles in acheving desired in crease in buccal mucoadhesion. Due to incorporation of SCMC along with Two critical polymers will enhance desired drug release in an improved way. This strategic approach elucidates the interplay between SCMC and material attributes (Carbopol 934, HPMC) in facilitating improved rates of diffusion for enhanced therapeutic outcomes. The study concluded that it's possible to create effective Dapsone buccal tablets, and their characteristics are largely determined by the polymers used.

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