Development and Assessment of Quick Release Mucoadhesive Buccal Tablets of Loratadine Utilizing Beta cyclodextrin Inclusion Complex Technique: A Formulation Study

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Abstract

The buccal mode of administration has various benefits, including increasing patient compliance and avoiding the first pass effects on the liver and GIT. The objective of the current study was to develop and assess mucoadhesive buccal tablets of the anti-histaminic drug loratadine, 10 mg. The inclusion complex (a kneading procedure) and direct compression methods are used to make the tablets. The mucoadhesive tablet formulations were created by combining different amounts of sodium starch glycolate, crospovidone, and beta-cyclodextrin as carriers and super disintegrants. By using FTIR and DSC investigations to check the components' compatibility with the medication, it was determined that there were no physicochemical interactions. The formulations were made in the following ratios: from F1 to F3, the dug to carrier (-cyclodextrin) ratio was (1:2), and from F4 to F6, the ratio was (1:4). And it was discovered that the ratio was 1:6 from F7 to F9. Dissolution was carried out in the USP dissolution apparatus-II (paddle) at a speed of 50 rpm and a temperature of 37±5 °C. The evaluation result of the formulations F-7 containing β-CD of ratio 1:6 and Crospovidone were selected as best formulation.

Key words: *Loratadine, Buccal tablets, beta-cyclodextrin, Crospovidone, SSG, FTIR, Dissolution, Mucoadhesion strength*

1. Introduction

The most advantageous mode of administration is oral since it is simple to consume, pain-free, adaptable (to accommodate a variety of medication options), and most importantly, patient-compliance. Buccal mucosal has robust vascularization and a high permeability for various APIs, in addition to avoiding the first-pass impact. The medicines' oral mucosa permeability, however, is insufficient for plasma concentration to rise to therapeutic levels. Transcellular and paracellular routes are the two main pathways involved. It is believed that most medicines are delivered by the paracellular pathway by passive diffusion in the buccal mucosa. Loratadine is an antihistamine with a long half-life that is highly selective for peripheral histamine H1-receptors and does not have the depressive effects on the central nervous system that are frequently linked with some of the older antihistamines. Loratadine will thus be a helpful addition to the medications currently on the market for the treatment of patients with allergic illnesses in whom a histamine H1-receptor antagonist is needed thanks to the convenience of once daily dosing. Loratadine has a 40% bioavailability, substantial first-pass hepatic metabolism, and an 8-hour half-life. As a result, a Loratadine buccal tablet will be created to stop first-pass metabolism and increase therapeutic effectiveness.

_2. Materials and Methods: _

A free sample of Loratadine was received from Tagoor laboratories Pvt.Ltd in India. Crospovidone, SSG, Carboxymethylcellulose-Sodium, beta-cyclodextrin, Magnesium stearate, Talc, ethyl cellulose, all the materials used were of analytical grade.

Methods:

COMPATABILITY STUDIES

Utilizing infrared spectroscopy with the Fourier transform, studies on the compatibility of pharmacological 10 excipients were conducted. The FTIR employed in this study is a Bruker Alpha II FTIR spectrometer with an 11 Attenuated Total Internal Reflectance (ATR) accessory made of zinc selenide crystal. From Figures 5 and 6, the 12 derived graphs for the medication and various excipients are provided below.

DSC

After stability investigations, the likelihood of any interactions between Loratadine and excipients in Buccal 16 tablets was evaluated by performing heat analysis using DSC research. After stability testing, the tablets of the optimized formulation F7 and the pure medication (loratadine) were used for DSC investigations. The thermal behavior of the samples was assessed using a DSC at a heating rate of 10^0C/min. The measurements were performed at a heating range of 30 to 200 ^{0}C under nitrogen atmosphere. DSC thermogram of Loratadine and optimized formulation F7 are shown in Figure respectively.

Kneading method (INCLUSION COMPLEX)

The required quantities of the drug (loratadine) and β-cyclodextrin were weighed accurately in a ratio of 1:1. Add a small amount of water: methanol (1:1) in a mortar to make a uniform cyclodextrin paste. Then add the drug powder to the paste in portions and mix continuously for three hours. The right amount of water: methanol mixture (1:1) was also added to obtain the correct paste consistency. This paste is dried in a hot air oven at 45-50°C. The dried compound is then ground into a powder, sieved through a No. 44 sieve, and stored in a sealed container until further use.

Method of preparation of Buccal Tablets of loratadine

The direct compression method was used to make the loratadine buccal tablets. Beta-cyclodextrin was used as a solubility enhancer (carrier) in various ratios, along with crospovidone, sodium starch glycolate as a super disintegrant, sodium-CMC as a mucoadhesive polymer, and lactose as diluents. Talc was employed as a glidant (flow booster) and mg. Stearate as a lubricant. All the

materials were thoroughly mixed in a mortar and pestle for 15 minutes before going into direct compression. The steps in this process were repeated for each of the formulations listed in Table 1. Then, using a 12-station multi-tooling tablet compression machine, the contents were weighed and compressed into buccal tablets of 250 mg apiece while maintaining ethyl cellulose as the backing layer.

Table I: Formulation for Buccal tablets

S.NO	INGREDIENTS	F1 (mg) 1:2	F2 (mg) 1:2	F3 (mg) 1:2	F4 (mg) 1:4	F5 (mg) 1:4	F6 (mg) 1:4	F7 (mg) 1:6	F8 (mg) 1:6	F9 (mg) 1:6
1	Loratadine	10	10	10	10	10	10	10	10	10
2	β-cyclodextrin	20	20	20	40	40	40	60	60	60
3	Crospovidone	8	-	4	8	-	4	8	-	4
4	SSG	-	8	4	-	8	4	-	8	4
5	Lactose	143	143	143	123	123	123	103	103	103
6	Sodium CMC	15	15	15	15	15	15	15	15	15
7	Talc	2	2	2	2	2	2	2	2	2
8	Magnesium stearate	2	2	2	2	2	2	2	2	2
9	Ethyl cellulose	50	50	50	50	50	50	50	50	50
Total weight of each tablet 250 (mg)										

Post-compression parameters

Weight Variation test:
A digital weighing balance was used to weigh each of ten Buccal tablets of each formulation both individually and collectively. Standard deviation was calculated together with the average weight of ten tablets. A reliable way to assess the homogeneity of the medication content is the weight change test.

Tablet Thickness:
Using vernier calipers, the thickness of each formulation was measured. Average values were computed using ten Buccal tablets from each batch.

Hardness:
This test is intended to determine the durability of tablets that might be harmed or broken during handling, storage, or transit. Three tablets from each batch were subjected to a hardness test using a Pfizer hardness tester, and the average values were computed. It is stated as kg/cm2.

Friability:
Due to the elimination of tiny particles from the surface, friability causes the tablet to weigh less in the container or package. To verify that the tablets can endure shocks during processing, handling, transit, and shipment, a quality control test is conducted as part of the manufacturing process. Typically, it is assessed using a Roche friabilator. Ten Winitial pills were weighed and

placed in the apparatus. They were struck every time the machine turned, and again when they plummeted six inches. The tablets (W-final) are weighed after this treatment has taken four minutes or 100 rotations, and the weight is compared to the starting weight. Tablet friability is determined by the loss through abrasion**.**

***In-vitro* Disintegration test**

Buccal tablets frequently disintegrate because of water being absorbed by super-disintegrants by capillary action, which causes swelling of the super-disintegrants and tablet disintegration. It has been demonstrated that adjusting the compaction force can change the disintegration duration by increasing or decreasing it. A Buccal pill was used in the test, and no supporting materials were used. From each batch, six pills were chosen at random and put into USP disintegration device baskets. The tablet totally dissolves in a matter of seconds, leaving no tangible material behind. Phosphate buffer pH 6.8 at 37°C served as the disintegration medium.

Uniformity of Drug content

By using a UV spectrophotometer, the amount of medication in the manufactured Buccal tablets was identified. A quantity equal to 10 mg of the medication was collected from ten of the batch's tablets, powdered, and dissolved in 100 cc of phosphate buffer, pH 6.8. Filtered solution was added, 1ml of the initial stock solution was diluted to a final volume of 10ml with phosphate buffer (pH 6.8), and the sample was then analyzed at 274nm against a blank. Each sample underwent a triple analysis.

***In-vitro* Dissolution studies**

Utilize the USP II dissolving tester in the paddle type to monitor the medication's release from the Buccal tablet. Since the tablet should only release the medication from one side, the impermeable backing membrane is positioned on that side of the tablet. The tablets are attached to a 2 cm by 2 cm glass slide using a cyanoacrylate adhesive solution. After that, add 500 ml of pH 6.8 phosphate buffer to the dissolve device and turn the paddle at 50 rpm while maintaining a temperature of 37± 0.5°C. At intervals of 15, 30, 45, 60, 75, 90, and 120 minutes up to 2 hours, 5 ml samples were obtained, and the same volume of fresh dissolving media was added in their place. The samples' drug release was examined by measuring the absorbance at 274nm using UV spectrophotometer.

Surface pH

To check for potential adverse effects in vivo, the surface pH of the three tablets of each formulation was calculated. Since the buccal mucosa may become irritated by an acidic or alkaline pH, we work to maintain the surface pH as neutral as possible. The initial step in the swelling process was to place the tablets in glass tubes containing 1 ml of phosphate buffer pH 6.8 and leave them there for 2 hours. After giving the electrode a minute to the surface of the tablet, measure the pH of the tablet's surface.

Swelling studies

Separate weights are used for the buccal pills. Placing the tablets in a petri dish with 5 ml of phosphate buffer (pH 6.8) bottom and the backing layer is visible from above. Ensure that the core of the tablet is completely submerged in and W1 as the starting weight will ensure that the side of the tablet closest to the buccal membrane is on the buffer solution. Using a coverslip, take the oral pill out of the petri dish after 30, 60, 90, and 120 minutes as directed. Next, thoroughly wipe away any remaining water from the surface with Whatman filter paper. The pill was then weighed again (W2) after it had grown larger.

Mucoadhesive strength

The ex vivo mucosal adhesion strength is calculated with a modified balance technique. Fresh sheep buccal mucosa was procured from the butcher and used two hours after the sheep died. A physical balance with two beams, a pan on the right side, and a glass slide suctioned to the bottom of a string stretched from the balance's left side made up the instrument. The tablets had been

affixed to this area of the surface. The 50 mL beaker containing the sheep buccal mucosa was placed on top of the 250 mL beaker containing phosphate buffer with a pH of 6.8 and maintained at 37ºC. Barely much buffer was left over to safeguard the buccal. The right pan was exactly five grammes heavier before the porcine buccal pill was placed there. Once the weight was taken off, the glass slide with the buccal pill attached fell downward. The swine's buccal mucosa membrane was to come into touch with the pill, and that contact had to last for five minutes. Weights were put to the right side of the pan after five minutes to help separate the tablet from the membrane. The weight that had collected on the right side was then reduced by 5 g. The quantity functioned as a barometer for the medication's bio adhesive potency.

In-vitro Diffusion studies

The diffusion cell's receptor compartment was filled with the formulated Buccal tablet carrying 10mg of medication, and the donor compartment was filled with pH 6.8 phosphate buffer (100ml), which will come into touch with the dialysis membrane. This diffusion cell was put on the magnetic stirrer with a magnetic bead in the receptor compartment. The dialysis membrane is where the medication first permeates and then it enters the receptor compartment. At intervals of 5, 10, 15, 30, 45, and 60 minutes, a solution of 2 ml is removed from the receptor compartment, and it is replenished with 2 ml of phosphate buffer to keep the sink in condition. By using a (Shimadzu) UV-Visible Spectrophotometer set at 274nm, samples' absorbance was examined**.**

3. Results and discussion:

Drug excipients compatibility studies: FT-IR spectrum of the pure drug (Loratadine) showed principle peaks at 2982.7 cm^{-1}, 2870.72 cm^{-1}, 1703.32 cm^{-1}, 28 1580.48 cm^{-1}, 1224.15 cm^{-1}, 1168.84 cm^{1}, 877.7cm^{-1}, characteristic to C-H stretching (aromatic ring), C=C 29 stretching, C=O stretching, C-N stretching (tertiary amine), O-H stretching , C=N stretching (pyridine), C-CL 30 stretching functional groups respectively. The IR spectrum of the drug-excipients mixture (Mixture 1-3) as shown in Table showed peaks of the above-mentioned functional groups at wavenumber almost like that of pure drug Loratadine. The FTIR characteristic of Loratadine peak results were found to be like the B.P. standard Loratadine peaks. This indicates that there was no chemical interaction or bonding or decomposition of Loratadine employed in the formulations. Hence, it was concluded that the drug and excipients of the formulations were compatible.

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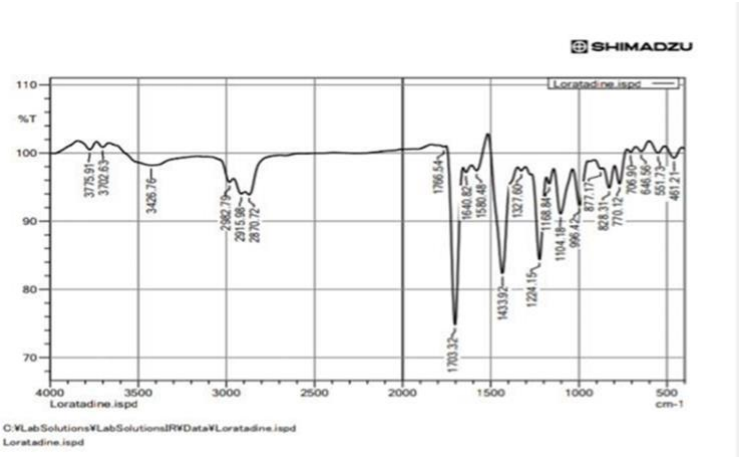

Figure No. 1: FTIR spectrum of loratadine standard

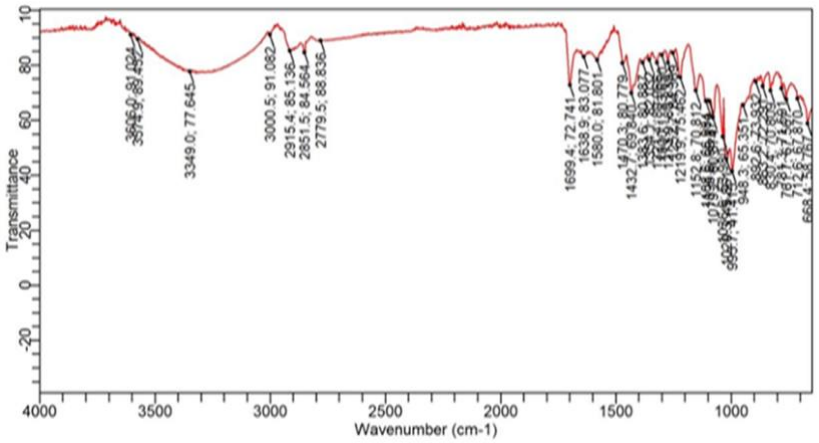

Figure No: 2: FTIR Spectrum of loratadine, polymers, and excipients (Physical Mixture 1)

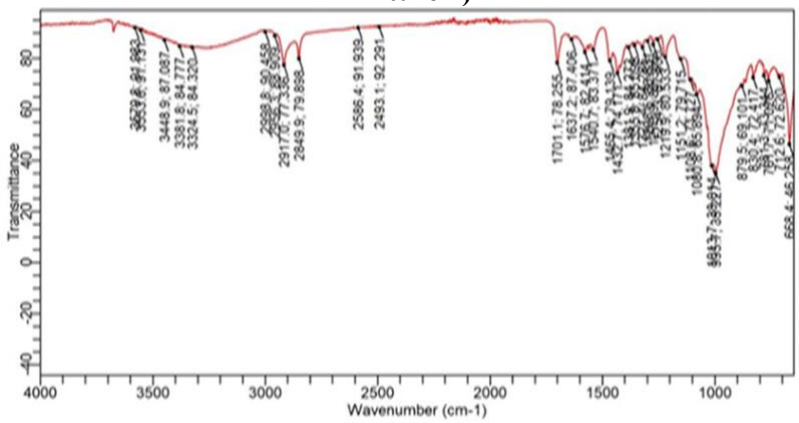

Figure No: 3: FTIR Spectrum of loratadine, polymers, and excipients (Physical Mixture 2)

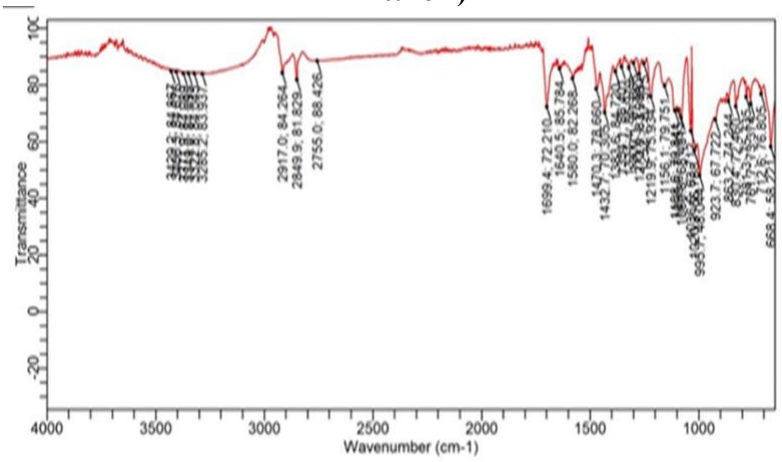

Figure No: 4: FTIR Spectrum of loratadine, polymers, and excipients (Physical Mixture 3)

Drug polymer compatibility studies using DSC: DSC experiments were conducted to investigate any potential physical interactions between the excipients and the medication. The melting point of the substance was indicated by the prominent endothermic peak that was visible in pure drug at 145.37°C. The sharp endothermic peak of sample loratadine was nearly to the standard peak of loratadine according to the BP monographs. The optimized formulation F7 after stability studies is taken and the thermal behavior of sample is determined using differential scanning calorimeter, endothermic peak obtained after stability studies is at 142.58°C. The

endotherm of the medication was not noticeably altered in Optimized buccal tablets. This led to the conclusion that, even after stability testing, there was no interaction between the medicine and excipients.

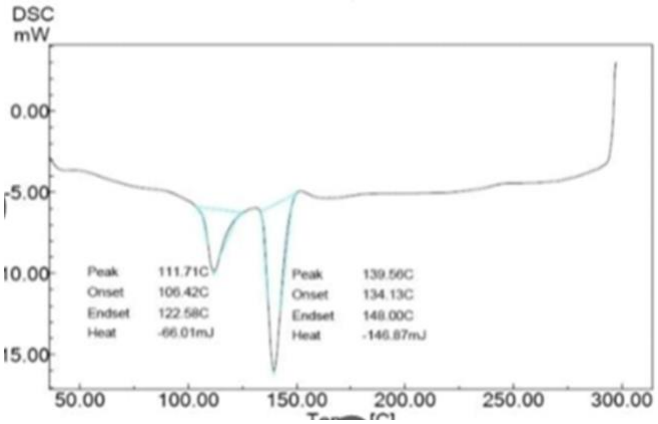

Figure No. 5 a. DSC thermogram of pure loratadine.

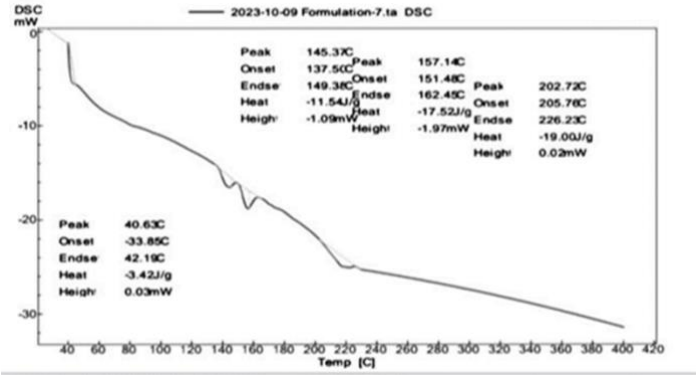

Figure No. 5 b. DSC thermogram of formulation F7

Post compression parameters*:* Weight variation, hardness, friability, thickness, disintegration, medication content, surface pH, swelling tests, and mucoadhesive strength were all assessed for the tablets. A key factor in medication release is the cohesiveness of tablets, which is measured by the tablet hardness test. It is one of the recognized techniques for figuring out how strong a tablet is. Tablets also need to be acceptable friable to sustain shocks during packing and transportation. Controlling the product's hardness will guarantee that it is both robust enough to resist handling without breaking or crumbling and not too hard to unnecessarily prolong the disintegration process.

DISINTEGRATION TIME: Disintegration rates of tablets were determined to be in the following order: beta-cyclodextrin (1:6) > (1:4) > (1:2) and super disintegrants CP > SSG. All formulations had disintegration times 49 ranging from 162.66 to 190.33 seconds**.** (Table 3).

SURFACE pH: To check for potential adverse effects in vivo, the surface pH of the Buccal tablets was measured. Because the buccal mucosa may become irritated by an acidic or alkaline pH. According to Table 3, the surface pH values ranged from 6.53 to 6.93, indicating that all formulations have an adequate pH between 6.5 and 7.5 for saliva.

MUCOADHESIVE STRENGTH: Buccal tablets were reported to have mucoadhesion ranging from 3.250.06 to 5.850.05gm (Table 3). The kind of polymer and the quantity of bioadhesive polymers utilized in the formulation were the main causes of the mucoadhesion.

DRUG CONTENT: The Percentage of drug content in the formulated tablets (F1- F9) was found to be 85.01±0.32 to 101.27±0.49% (Table 3) indicating that the drug was uniformly distributed.

Table-II: Evaluation of Physical parameters for formulated tablets

FORMULATION CODE (n=10)	WEIGHT VARIATION (gm) ± SD	HARDNESS (kg/cm2) ± SD	THICKNESS (mm) ± SD (n=3)	FRIABILITY (%) ± SD (n=10)
F-1	245.16±0.75	3.4±0.1	2.74±0.01	0.34±0.01
F-2	251.46±0.35	3.96±0.05	3.24±0.01	0.28±0.01
F-3	248.1±0.88	3.95±0.1	2.96±0.01	0.29±0.03
F-4	245.03±0.50	3.16±0.11	2.78±0.01	0.32±0.02
F-5	250.83±0.89	3.93±0.15	3.18±0.01	0.29±0.03
F-6	247.1±0.45	3.86±0.15	2.84±0.02	0.27±0.02
F-7	246.06±0.77	2.96±0.20	2.71±0.01	0.44±0.02
F-8	249.23±0.40	3.8±0.1	2.98±0.02	0.28±0.01
F-9	247.86±0.47	3.46±0.15	2.81±0.01	0.26±0.01

Table-III: Evaluation of Physical parameters for formulated tablets

FORMULATION CODE	DISINTEGRATION TIME (sec) ± SD	SURFACE pH ± SD	MUCOADHESION STRENGTH (gm) ± SD	DRUG CONTENT (%)
F-1	175.66±2.08	6.63±0.05	5.45±0.08	93.77±0.32
F-2	178.33±1.52	6.62±0.09	4.05±0.14	99.39±0.53
F-3	182.33±2.08	6.53±0.10	3.25±0.06	85.01±0.32
F-4	170.66±2.51	6.76±0.12	5.75±0.05	97.52±0.32
F-5	168.66±2.51	6.83±0.08	3.85±0.21	95.64±0.32
F-6	184.33±1.52	6.76±0.06	3.60±0.04	91.89±0.53
F-7	162.66±1.52	6.84±0.05	5.85±0.05	93.77±0.26
F-8	176.66±2.08	6.72±0.08	3.90±0.21	101.27±0.49
F-9	190.33±2.88	6.93±0.05	3.90±0.08	88.14±0.08

SWELLING STUDIES: Swelling tests were conducted on all formulations (F1 to F9) for 2 hours at various time intervals (30 min, 60 min, 90 min, and 120 min, respectively), and results showed that the range of swelling was 26.76 ± 1.54 to 46.43±1.37 at 30 min, 56.55±1.40 to 66.85±0.93 at 60 min, 72.41±1.01 to 82.42±1.08 at 90 min, and 84.73±1.75 to 96. After being plotted on the x and y axis, respectively, it was discovered that the length in minutes and the % swelling index were directly proportional to one another (Figure 6). As a result, it was discovered that the tablets' swelling grew worse with time.

Table No IV: % Swelling index of formulated floating tablets F1-F9

FORMULATION CODE	After 30min	After 60min	After 90min	After 120min
F-1	29.38±0.74	61.29±1.10	79.89±0.97	87.83±0.74
F-2	26.76±1.58	59.75±1.48	76.82±0.88	84.84±1.56
F-3	28.79±0.63	62.49±1.88	75.64±1.03	86.71±0.53
F-4	33.43±1.81	66.85±0.93	78.83±1.15	89.73±1.71
F-5	32.39±1.60	56.55±1.40	72.41±1.01	84.73±1.75
F-6	34.74±1.36	63.03±1.06	77.62±0.46	92.59±1.24
F-7	46.43±1.37	65.52±0.83	79.32±1.78	96.32±1.78
F-8	41.61±1.34	64.72±1.09	82.42±1.08	92.64±1.23
F-9	39.62±1.50	65.83±1.49	81.46±1.52	95.79±1.40

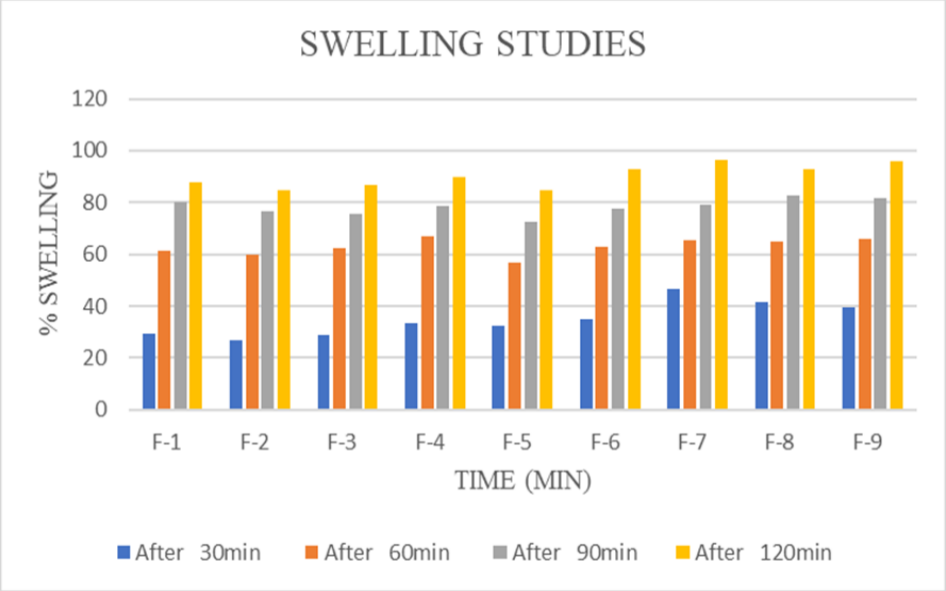

Figure No :6 Swelling index comparison graph F1-F9

In- vitro* dissolution study*: Dissolution testing is a crucial step in developing solid dosage forms for the pharmaceutical industry. In vitro release tests were performed on the Buccal tablets of formulations (F1-F9) using a dissolution equipment USP type-II at 50 rpm and phosphate buffer pH 6.8 (500 ml) as the dissolve medium. Tables 5 and 6 display the medication release information that was discovered for formulations F1 to F9. Plots of the cumulative% drug released over time for various formulations were made on the y and x axis, respectively (Figure 7). After 120 minutes, it was discovered that the drug release from the formulations F-7, F-8, and F-9, which contain beta-cyclodextrin in a 1:6 ratio, was 80.02±0.56%, 76.79±0.23%, and 75.76±0.39%. After 120 minutes, it was discovered that the drug release from the formulations F-4, F-5, and F-6, which contain beta-cyclodextrin in a 1:4 ratio, was 75.18± 1.24%, 74.01± 0.63%, and 73.13± 0.92%. After 120 minutes, it was discovered that the drug release from the formulations F-1, F-2, and F-3, which contain beta-cyclodextrin in a 1:2 ratio, was 69.89±0.85%, 72.48±0.65%, and 68.42±0.79%. When compared to other formulations, the F-7 formulation's (80.02±0.56%) drug release was rapid. This might be explained by the polymer expanding up more as beta-cyclodextrin concentration Graph showing the results of in-vitro drug diffusion studies conducted on Buccal tablets containing

loratadine for improved formulation (F-7 to F-9) The improved formulations (F7, F8, and F9) were then used to examine permeation across a synthetic cellophane membrane. Within 60 minutes, Formulation F7, which contained beta cyclodextrin and crospovidone in a 1:6 ratio, diffused the drug up to 76.005±0.360%. Beta-cyclodextrin and sodium starch glycolate, in Formulation F8, diffused the medication up to 73.647±0.186% in 60 minutes. Within 60 minutes, Formulation F9, which contained beta-cyclodextrin in a 1:6 ratio with crospovidone and SSG, diffused the drug up to 74.313±0.367%within 60 min.

Table No V: Cumulative Drug Release F1-F5

TIME (min)	F-1	F-2	F-3	F-4	F-5
0	0	0	0	0	0
15	15.87±0.74	15.43±0.39	13.52±0.38	16.46±0.36	16.16±0.75
30	23.80±1.05	34.07±1.50	16.16±0.49	35.98±0.24	35.54±1.00
45	35.69±0.76	43.76±1.05	26.73±0.64	44.50±0.60	43.47±1.27
60	43.76±0.67	49.19±1.33	34.51±1.17	51.69±1.06	49.19±0.48
75	54.33±1.10	58.15±1.05	43.47±1.03	61.08±1.47	61.97±1.61
90	64.31±0.64	66.37±0.80	56.53±0.90	69.45±1.46	67.84±0.78
120	69.89±0.85	72.48±0.65	68.42±0.79	75.18±1.24	74.01±0.63

Table No VI: Cumulative Drug Release F6-F9

TIME (min)	F-6	F-7	F-8	F-9
0	0	0	0	0
15	15.43±0.48	17.48±0.23	16.90±0.47	16.60±0.47
30	33.78±1.05	26.44±0.47	25.85±0.37	23.80±0.71
45	44.35±0.59	36.42±0.47	33.34±0.60	32.60±0.60
60	50.81±0.62	49.19±0.62	41.12±0.50	38.62±0.37
75	60.50±0.93	65.49±0.47	51.84±0.48	50.81±0.49
90	69.89±0.99	72.83±0.36	69.01±0.37	62.41±0.36
120	73.12±0.92	80.02±0.56	76.79±0.23	75.76±0.39

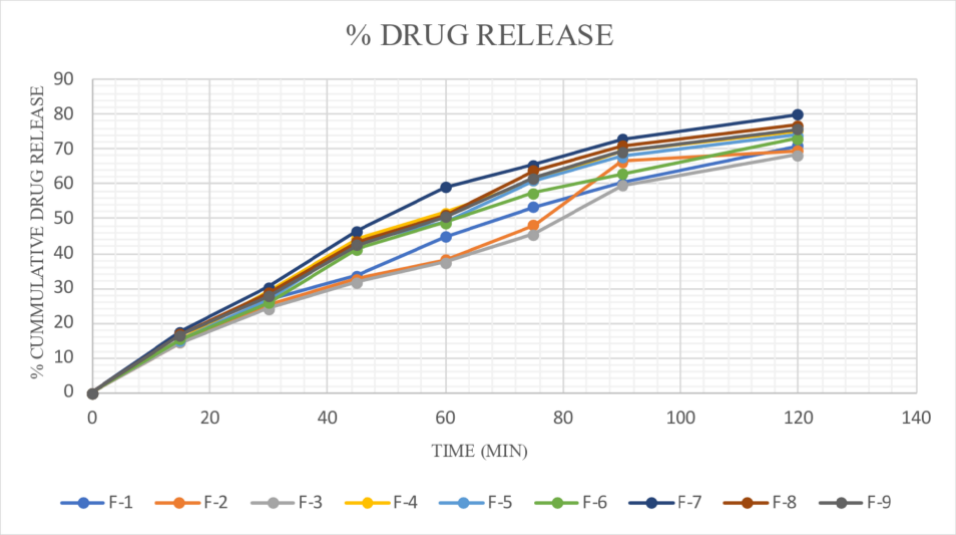

Figure No: 7 *In-vitro* Dissolution profile for F1-F9 Formulations

4. CONCLUSION:

The goal of the current research was to create and assess Buccal tablets to treat Allergic rhinitis and Chronic urticaria. The medication to carrier (-cyclodextrin) ratio was determined to be (1:2) for formulations F1 to F3, (1:4) for formulations F4 to F6, and (1:6) for formulations F7 to F9. A total of 9 formulations were developed. Crospovidone is utilized at 4% concentration in formulations F1, F4, F7, sodium starch glycolate is used at 4% concentration in formulations F2, F5, F8, and both substances are combined in formulations F3, F6, and F9. FT-Pure drug and formulation IR spectra showed compatibility between the drug and excipients. The results of preformulation and post formulation studies were within the limits. The drug content uniformity of all the formulations F-1 to F-9 was determined. Among all F-7 to F-9 batch had shown the rapid drug release when compared to the other formulations All the formulations released more than 69% of the medication by 120 minutes. In terms of drug content, in-vitro disintegration time, in-vitro drug release, and friability, formulation (F-7) was deemed to be superior to the other formulations. The formulation F-7 was deemed to be the best for Buccal tablets because it demonstrated the highest drug release (up to 80.02%) of all the formulations examined in this study. The formulation F7, which contains beta-cyclodextrin in a 1:6 ratio and crospovidone, showed the 44 highest rate of drug penetration within 60 minutes, at 76.005±0.360%. Finally, it can be concluded that Buccal tablets can be considered as a promising drug delivery system which showed rapid drug release of Loratadine.

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