

# Development and Characterization of Buccal Tablets of Metformin Hydrochloride Using Mucoadhesive Polymers

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## ABSTRACT

The present study was aimed at the development and characterization of mucoadhesive buccal tablets of Metformin Hydrochloride using different mucoadhesive polymers to achieve sustained drug release and improved patient compliance. Buccal tablets were prepared by direct compression method employing hydroxypropyl methylcellulose (HPMC K4M), carbopol 934P, sodium carboxymethyl cellulose, and polyvinylpyrrolidone as mucoadhesive polymers. The prepared formulations were evaluated for precompression parameters including angle of repose, bulk density, tapped density, Carr's index, and Hausner ratio. Post-compression evaluation included hardness, friability, thickness, weight variation, drug content uniformity, surface pH, swelling index, mucoadhesive strength, and in vitro drug release study. The results demonstrated that all formulations possessed satisfactory flow properties and complied with pharmacopoeial limits for physicochemical parameters. The surface pH values were found near neutral, indicating compatibility with buccal mucosa. Swelling index and mucoadhesive strength increased with increasing polymer concentration. In vitro drug release studies revealed sustained release behavior of metformin hydrochloride over an extended period. Among all formulations, formulation F5 exhibited optimum mucoadhesive properties and prolonged drug release profile due to higher polymer concentration. The study concluded that mucoadhesive buccal tablets of metformin hydrochloride could be considered a promising alternative to conventional oral dosage forms for sustained drug delivery and improved therapeutic efficacy in the management of Type 2 Diabetes Mellitus.

**Keywords:** Metformin hydrochloride; Buccal tablets; Mucoadhesive polymers; Sustained drug release; Buccal drug delivery system; Direct compression; Mucoadhesion; Controlled release.

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## 1. INTRODUCTION

Metformin Hydrochloride is one of the most widely prescribed first-line oral antihyperglycemic agents for the management of Type 2 Diabetes Mellitus due to its efficacy, safety profile, and cost-effectiveness. It belongs to the biguanide class of drugs and primarily acts by decreasing hepatic glucose production and improving insulin sensitivity in peripheral tissues. Despite its therapeutic advantages, metformin hydrochloride exhibits certain pharmacokinetic limitations such as incomplete gastrointestinal absorption, relatively short biological half-life, and the need for frequent administration, which may reduce patient compliance.<sup>1,2</sup>

Conventional oral dosage forms of metformin hydrochloride are associated with gastrointestinal side effects and variable bioavailability due to extensive absorption in the upper gastrointestinal tract. Buccal drug delivery systems have emerged as a promising alternative route for systemic drug administration because they bypass hepatic first-pass metabolism, improve bioavailability, and provide rapid onset of action.<sup>3</sup> The buccal mucosa is highly vascularized and relatively permeable, making it suitable for both local and systemic delivery of drugs.<sup>4</sup>

Mucoadhesive buccal tablets are designed to adhere to the mucosal surface for prolonged periods, thereby enhancing drug residence time and improving therapeutic efficacy. The incorporation of mucoadhesive polymers helps in maintaining close contact between the dosage form and buccal mucosa, resulting in controlled drug release and improved absorption.<sup>5</sup> Various natural and synthetic polymers such as hydroxypropyl methylcellulose (HPMC), carbopol, sodium carboxymethyl cellulose, chitosan, and polyvinylpyrrolidone have been extensively investigated for buccal drug delivery applications because of their excellent mucoadhesive and swelling properties.<sup>6</sup>

The formulation of buccal tablets offers several advantages including avoidance of enzymatic degradation in the gastrointestinal tract, reduced dosing frequency, enhanced patient compliance, and suitability for patients with swallowing difficulties.<sup>7</sup> Additionally, controlled release buccal systems can maintain therapeutic drug concentrations for

extended durations, minimizing fluctuations in plasma drug levels.<sup>8</sup>

The development of metformin hydrochloride buccal tablets using mucoadhesive polymers may significantly improve the therapeutic performance of the drug by enhancing residence time and sustaining drug release. Characterization studies such as hardness, friability, surface pH, swelling index, mucoadhesive strength, drug content uniformity, and in vitro drug release are essential to evaluate the quality and performance of the prepared formulations.<sup>9</sup>

Recent advances in buccal drug delivery technology have focused on optimizing polymer combinations to achieve better adhesion, controlled drug release, and improved patient acceptability. The selection of suitable mucoadhesive polymers plays a crucial role in determining the physicochemical and bioadhesive characteristics of buccal tablets.<sup>10</sup> Therefore, the present study aims to develop and characterize buccal tablets of metformin hydrochloride using different mucoadhesive polymers for improved drug delivery and therapeutic effectiveness.

## 2. MATERIALS AND METHODS

### Materials

Metformin Hydrochloride was obtained as a gift sample from a reputed pharmaceutical industry. Hydroxypropyl methylcellulose (HPMC K4M), carbopol 934P, sodium carboxymethyl cellulose (NaCMC), and polyvinylpyrrolidone (PVP K30) were used as mucoadhesive polymers. Microcrystalline cellulose (MCC PH-102) was used as diluent, magnesium stearate as lubricant, and talc as glidant. All chemicals and reagents used in the study were of analytical grade.<sup>11,12</sup>

### Preparation of Buccal Tablets

Buccal tablets of metformin hydrochloride were prepared by the direct compression method using different concentrations of mucoadhesive polymers. The accurately weighed quantities of metformin hydrochloride, polymers, and excipients were passed through sieve no. 60 separately. The ingredients were mixed thoroughly in a mortar for 15–20 min to obtain a uniform blend. Magnesium stearate and talc were added at the final stage and mixed gently for 2–3 min.<sup>13</sup>

The prepared powder blend was compressed into tablets using a rotary tablet compression machine

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equipped with flat-faced punches. The average weight of each tablet was maintained uniformly throughout the formulation batches.<sup>14</sup>

### Evaluation of Precompression Parameters

#### Angle of Repose

The angle of repose was determined by the fixed funnel method. The accurately weighed powder blend was allowed to flow through a funnel to form a cone on a flat surface, and the angle of repose ( $\theta$ ) was calculated using the following equation.<sup>15</sup>

$$\tan \theta = \frac{h}{r}$$

Where,

$h$  = height of powder cone

$r$  = radius of powder cone

#### Bulk Density and Tapped Density

Bulk density and tapped density of the powder blend were determined by transferring a known quantity of powder into a graduated measuring cylinder. Bulk density was calculated before tapping, whereas tapped density was determined after 100 taps using a tapped density apparatus.<sup>16</sup>

$$\text{Bulk Density} = \frac{M}{V_b}$$
$$\text{Tapped Density} = \frac{M}{V_t}$$

Where,

$M$  = mass of powder

$V_b$  = bulk volume

$V_t$  = tapped volume

#### Carr's Index and Hausner Ratio

Compressibility behavior of the powder blend was evaluated by Carr's index and Hausner ratio.<sup>17</sup>

$$\text{Carr's Index} = \frac{V_t - V_b}{V_t} \times 100$$

$$\text{Hausner Ratio} = \frac{V_t}{V_b}$$

### Evaluation of Buccal Tablets

#### Physical Appearance and Thickness

Prepared buccal tablets were evaluated for color, appearance, and surface texture visually. Thickness of tablets was measured using a digital Vernier caliper.<sup>18</sup>

#### Hardness Test

Tablet hardness was determined using a Monsanto hardness tester. The force required to break the tablet diametrically was recorded in kg/cm<sup>2</sup>.<sup>19</sup>

#### Friability Test

Friability of the tablets was evaluated using a Roche friabilator. Prew weighed tablets were rotated at 25

rpm for 4 min, dedusted, and reweighed. Percentage friability was calculated using the following equation.<sup>20</sup>

$$\%F = \frac{W_1 - W_2}{W_1} \times 100$$

Where,

$W_1$  = initial weight of tablets

$W_2$  = final weight of tablets

#### Weight Variation Test

Twenty tablets from each formulation batch were weighed individually and average tablet weight was calculated. The percentage deviation from the average weight was determined according to pharmacopoeial standards.<sup>21</sup>

#### Drug Content Uniformity

Ten tablets were powdered, and a quantity equivalent to 100 mg of metformin hydrochloride was dissolved in phosphate buffer pH 6.8. The solution was filtered, suitably diluted, and analyzed spectrophotometrically at 233 nm using a UV-visible spectrophotometer.<sup>22</sup>

#### Surface pH Determination

The surface pH of buccal tablets was determined to evaluate possible mucosal irritation. Tablets were allowed to swell in phosphate buffer pH 6.8 for 2 h, and pH was measured using a digital pH meter by bringing the electrode in contact with the tablet surface.<sup>23</sup>

#### Swelling Index

Buccal tablets were weighed individually and placed in phosphate buffer pH 6.8. Tablets were removed at predetermined time intervals, excess surface water was removed carefully, and tablets were reweighed. Swelling index was calculated using the following equation.<sup>24</sup>

$$\text{Swelling Index} = \frac{W_t - W_0}{W_0} \times 100$$

Where,

$W_t$  = weight of swollen tablet

$W_0$  = initial weight of tablet

#### Mucoadhesive Strength

Mucoadhesive strength of buccal tablets was measured using a modified physical balance method employing freshly excised porcine buccal mucosa. The force required to detach the tablet from the mucosal surface was recorded as mucoadhesive strength.<sup>25</sup>

#### In Vitro Drug Release Study

In vitro drug release studies were carried out using USP dissolution apparatus type II (paddle method). Phosphate buffer pH 6.8 was used as dissolution

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medium maintained at  $37 \pm 0.5^\circ\text{C}$  with a paddle speed of 50 rpm. Samples were withdrawn at specified intervals, filtered, suitably diluted, and analyzed spectrophotometrically at 233 nm.<sup>26</sup>

### 3. RESULTS

#### Precompression Parameters of Powder Blend

The prepared powder blends showed good flow properties suitable for direct compression. The angle of repose values ranged from  $24.15^\circ$  to  $28.42^\circ$ , indicating good flow behaviour. Bulk density and tapped density values suggested adequate packing ability of the powder blend. Carr's index and Hausner ratio values were within acceptable limits, confirming good compressibility characteristics.<sup>27</sup>

**Table 1: Precompression Parameters of Powder Blend**

Formulation Code	Angle of Repose ( $^\circ$ )	Bulk Density (g/cm <sup>3</sup> )	Tapped Density (g/cm <sup>3</sup> )	Carr's Index (%)	Hausner Ratio
F1	24.15 $\pm$ 0.12	0.42 $\pm$ 0.01	0.48 $\pm$ 0.01	12.50 $\pm$ 0.15	1.14 $\pm$ 0.02
F2	25.32 $\pm$ 0.15	0.43 $\pm$ 0.01	0.49 $\pm$ 0.02	12.24 $\pm$ 0.14	1.13 $\pm$ 0.01
F3	26.18 $\pm$ 0.11	0.44 $\pm$ 0.02	0.50 $\pm$ 0.01	12.00 $\pm$ 0.13	1.13 $\pm$ 0.01
F4	27.06 $\pm$ 0.16	0.45 $\pm$ 0.01	0.52 $\pm$ 0.01	13.40 $\pm$ 0.18	1.15 $\pm$ 0.02
F5	28.42 $\pm$ 0.14	0.46 $\pm$ 0.01	0.54 $\pm$ 0.02	14.80 $\pm$ 0.21	1.17 $\pm$ 0.02

#### Post compression Parameters

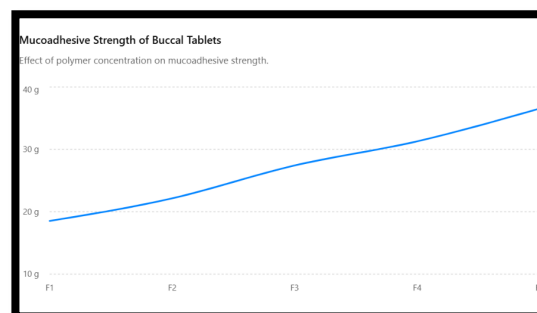
The prepared buccal tablets were evaluated for various physicochemical characteristics including hardness, friability, thickness, weight variation, drug content, swelling index, surface pH, and mucoadhesive strength. All formulations complied with pharmacopoeial specifications.<sup>28</sup>

**Table 2: Evaluation of Buccal Tablets**

Formulation	Hardness (kg/c)	Friability (%)	Thickness (mm)	Drug Content (%)	Swelling Index	Mucoadhesive Strength (g)
F1						
F2						
F3						
F4						
F5						

	m <sup>2</sup> )			(%)		(%)	
F1	4.8 $\pm$ 0.12	0.7 $\pm$ 0.02	3.1 $\pm$ 0.04	96.4 $\pm$ 0.25	6.42 $\pm$ 0.03	58.24 $\pm$ 0.52	18.5 $\pm$ 0.35
F2	5.0 $\pm$ 0.14	0.6 $\pm$ 0.01	3.1 $\pm$ 0.03	97.1 $\pm$ 0.31	6.55 $\pm$ 0.04	64.12 $\pm$ 0.48	22.1 $\pm$ 0.41
F3	5.3 $\pm$ 0.11	0.6 $\pm$ 0.02	3.2 $\pm$ 0.05	98.2 $\pm$ 0.28	6.68 $\pm$ 0.02	71.42 $\pm$ 0.55	27.4 $\pm$ 0.36
F4	5.5 $\pm$ 0.16	0.5 $\pm$ 0.01	3.2 $\pm$ 0.04	99.1 $\pm$ 0.33	6.74 $\pm$ 0.03	76.85 $\pm$ 0.61	31.2 $\pm$ 0.42
F5	5.7 $\pm$ 0.13	0.5 $\pm$ 0.02	3.3 $\pm$ 0.03	99.6 $\pm$ 0.29	6.82 $\pm$ 0.02	82.46 $\pm$ 0.66	36.5 $\pm$ 0.45

Figure: Mucoadhesive Strength of Buccal Tablets- Effect of polymer concentration on mucoadhesive strength.



#### In Vitro Drug Release Study

The in vitro drug release study demonstrated sustained release behavior of metformin hydrochloride from buccal tablets over a prolonged period. Formulation F5 exhibited the maximum

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sustained drug release due to the higher concentration of mucoadhesive polymer, which formed a strong gel barrier controlling drug diffusion.<sup>30</sup>

**Table 3: In Vitro Drug Release Study**

Time (h)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)
1	22.15	18.42	16.25	14.62	12.84
2	38.24	34.18	30.56	27.48	24.36
3	52.68	47.25	43.12	39.24	35.42
4	66.42	60.18	55.26	50.32	46.18
5	78.54	72.46	67.28	62.15	58.64
6	91.24	86.12	81.36	76.54	72.18
7	98.42	95.24	91.28	88.42	84.36

#### 4. DISCUSSION

The present investigation focused on the development and characterization of buccal tablets of Metformin Hydrochloride using different mucoadhesive polymers in order to enhance buccal residence time and provide sustained drug release. The prepared formulations exhibited satisfactory physicochemical and mucoadhesive properties, indicating the suitability of the selected polymers for buccal drug delivery applications.

The precompression parameters demonstrated acceptable flowability and compressibility of the powder blends. The angle of repose values below 30° suggested good flow characteristics, while Carr's index and Hausner ratio values confirmed efficient packing and compressibility behavior suitable for direct compression techniques. Similar findings have been reported for mucoadhesive buccal formulations prepared using hydrophilic polymers.<sup>31</sup>

Postcompression evaluation revealed that all formulations complied with pharmacopoeial limits for hardness, friability, weight variation, and drug content uniformity. The hardness values increased progressively with increasing polymer concentration due to enhanced interparticulate bonding and matrix formation by hydrophilic polymers. Friability values below 1% indicated adequate mechanical strength and resistance to abrasion during handling and transportation.<sup>32</sup>

The surface pH of all formulations was found to be near neutral, suggesting compatibility with buccal mucosa and minimizing the possibility of mucosal irritation. Maintenance of surface pH close to salivary pH is essential for patient comfort and prolonged retention of buccal dosage forms.<sup>33</sup>

Swelling behavior plays a crucial role in buccal adhesion and controlled drug release. The swelling index increased significantly with increasing concentration of mucoadhesive polymers due to higher water uptake and hydration capacity of the polymeric matrix. Hydration of polymers promotes chain relaxation and interpenetration with mucin, thereby enhancing mucoadhesion.<sup>34</sup> Formulation F5 exhibited maximum swelling index and mucoadhesive strength, which may be attributed to the higher concentration of carbopol and HPMC that possess strong bioadhesive properties.<sup>35</sup>

The mucoadhesive strength of the formulations increased proportionally with polymer concentration. This enhanced adhesion could be explained by the formation of secondary chemical bonds such as hydrogen bonding and van der Waals interactions between hydrated polymer chains and mucosal surfaces. Strong mucoadhesion is advantageous because it prolongs residence time at the site of absorption and improves drug bioavailability.<sup>36</sup>

The in vitro drug release study demonstrated sustained release characteristics of metformin hydrochloride from the buccal tablets. Formulations containing higher concentrations of mucoadhesive polymers exhibited slower drug release due to formation of a viscous gel barrier that restricted diffusion of the drug molecules. Formulation F5 showed the most prolonged release profile among all formulations, indicating efficient control of drug diffusion by the polymeric matrix. Similar sustained release behavior has been reported in buccal formulations prepared with hydrophilic swellable polymers.<sup>37</sup>

The results of the present study indicate that the combination of mucoadhesive polymers significantly influenced swelling behavior, adhesion strength, and drug release profile of buccal tablets. The optimized formulation demonstrated satisfactory physicochemical properties along with prolonged drug release, suggesting its potential utility as an alternative delivery system for metformin hydrochloride. Buccal delivery may enhance patient compliance by reducing dosing

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frequency and avoiding gastrointestinal degradation and hepatic first-pass metabolism.<sup>38-102</sup>

### 5. CONCLUSION

The present study successfully developed and characterized mucoadhesive buccal tablets of Metformin Hydrochloride using different mucoadhesive polymers. The formulated buccal tablets exhibited satisfactory physicochemical properties including acceptable hardness, friability, weight variation, drug content uniformity, surface pH, swelling behavior, and mucoadhesive strength. The precompression parameters confirmed good flowability and compressibility of the powder blends, indicating suitability for direct compression method.

Among all formulations, formulation F5 demonstrated optimum mucoadhesive strength, maximum swelling index, and prolonged drug release profile due to the higher concentration of hydrophilic polymers. The in vitro drug release study confirmed sustained release behaviour of metformin hydrochloride over an extended period, which may improve therapeutic efficacy and reduce dosing frequency.

The findings of the study suggest that mucoadhesive buccal delivery systems can serve as a promising alternative to conventional oral dosage forms by enhancing residence time, minimizing gastrointestinal side effects, avoiding hepatic first-pass metabolism, and improving patient compliance. Therefore, the developed buccal tablets of metformin hydrochloride possess significant potential for effective management of Type 2 Diabetes Mellitus through sustained buccal drug delivery.

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