

Research Article

DESIGN AND EVALUATION OF BUCCAL TABLETS OF PENTAZOCINE

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ABSTRACT

Among the various routes of drug delivery, the oral route is perhaps the most preferred by patients and clinicians alike. However, peroral administration of drugs has disadvantages, such as hepatic first-pass metabolism and enzymatic degradation within the gastrointestinal tract (GIT). So, there has been a growing interest in the use of delivery of therapeutic agent through various transmucosal routes to provide a therapeutic amount of drug to the proper site in body to promptly achieve and then maintain the desired concentration. In the present work buccal tablets of Pentazocine was prepared by direct compression method by using combinations of polymers HPMC K4M, Sodium CMC and carbopol 934p. The buccal tablets were evaluated for physical parameters like appearance, hardness, thickness, weight variation, friability, swelling index and surface pH; biological parameter-mucoadhesive strength; and other parameters such as drug content uniformity, in vitro release, short-term stability and drug excipient interactions (FTIR). Among the twelve formulations, the formulation BP1 containing Sodium CMC (33.33% w/w of matrix layer) and carbopol 934p (0% w/w of matrix layer) was found to be promising, which showed t 25%, t 50% and t 70% values of 0.30, 3.12 and 5.24h respectively and in vitro drug release of 89.77% in 8 h along with satisfactory bioadhesion strength (7.70 g). Stability studies on the promising formulations indicated that there are no significant changes in drug content and in vitro dissolution characteristics ($p < 0.05$). Infrared-spectroscopic studies indicated that there are no drug-excipient interactions. The prepared buccal tablets of Pentazocine stayed in the buccal for a longer period of time, which indicate a potential use of mucoadhesive tablets of Pentazocine treating blood pressure.

Keywords: Mucoadhesive buccal tablets Pentazocine, carbopol 934p, Hydroxy propyl methyl K4M, sodium CMC, bioadhesive strength, in vitro dissolution.

INTRODUCTION

Among the various routes of drug delivery, the oral route is perhaps the most preferred by patients and clinicians alike. However, peroral administration of drugs has disadvantages, such as hepatic first-pass metabolism and enzymatic degradation within the gastrointestinal tract (GIT). So, there has been a growing interest in the use of delivery of therapeutic agent through various transmucosal routes to provide a therapeutic amount of drug to the proper site in body to promptly achieve and then maintain the desired concentration. Consequently, other absorptive mucosa is considered as potential sites for drug administration. Transmucosal routes of drug delivery (i.e. the mucosal linings of the oral, nasal, rectal, vaginal and ocular cavities) offer distinct advantages over peroral administration for systemic effect.¹

The unique environment of the oral cavity offers its potential as a site for drug delivery. These advantages include:

- 1) The drug is not subjected to the destructive acidic environment of the stomach.
- 2) Therapeutic serum concentration of the drug can be achieved more rapidly.
- 3) The drug enters the general circulation without first passing through the liver.²

In general, drugs penetrate the mucous membrane by simple diffusion and are carried in the blood, which richly supplies the

salivary glands and their ducts into the systemic circulation via the jugular vein. Active transport, pinocytosis and passage through aqueous pores usually play only insignificant roles in moving drugs across the oral mucosa. 3 Two sites within the buccal cavity have been used for drug administration. Using the sublingual route, in this the medication is placed under the tongue, usually in the form of rapidly dissolving tablet. The second anatomic site for drug administration is between the cheek and gingival.

Mucoadhesive drug delivery systems:

Bioadhesion can be described as adhesion of artificial substances to biological substrates such as adhesion of polymers to skin or other soft tissue.

These may be defined as drug delivery systems, which utilize the property of bioadhesion of certain water soluble polymers which become adhesive on hydration and hence can be used for targeting of drug to particular regions of body for extended periods of time.³

The mucoadhesive drug delivery system includes following:

1. Buccal drug delivery system
2. Rectal delivery system
3. Oral delivery system
4. Nasal delivery system
5. Vaginal delivery system
6. Ocular delivery system

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Table 1: Comparison of some routes for systemic drug delivery available to the formulation scientist

| Parameters | Gastrointestinal | Dermal | Nasal | Oral mucosal | Vaginal |
|-----------------------|------------------|--------|-------|--------------|---------|
| Accessibility | + | +++ | ++ | ++ | + |
| Surface area | +++ | +++ | + | ++ | +++ |
| Surface environment | + | ++ | + | +++ | + |
| Permeability | +++ | + | +++ | ++ | +++ |
| Reactivity | ++ | ++ | + | +++ | ++ |
| Vascular drainage | +++ | + | +++ | ++ | +++ |
| Firstpass clearance | + | +++ | +++ | +++ | + |
| Patient acceptability | ++ | +++ | ++ | +++ | ++ |

(+) poor, (++) good, (+++) excellent.

OVERVIEW OF ORAL CAVITY:

Oral cavity is that area of mouth delineated by the lips, cheeks, hard palate, soft palate and floor of mouth. The oral cavity consists of two regions.

1. Outer oral vestibule, which is bounded by cheeks, lips, teeth and gingival.
2. Oral cavity proper, which extends from teeth and gums back to the faces with the roof comprising the hard and soft palate. The tongue projects from the floor of the cavity.⁴



Figure No 1: Oral cavity

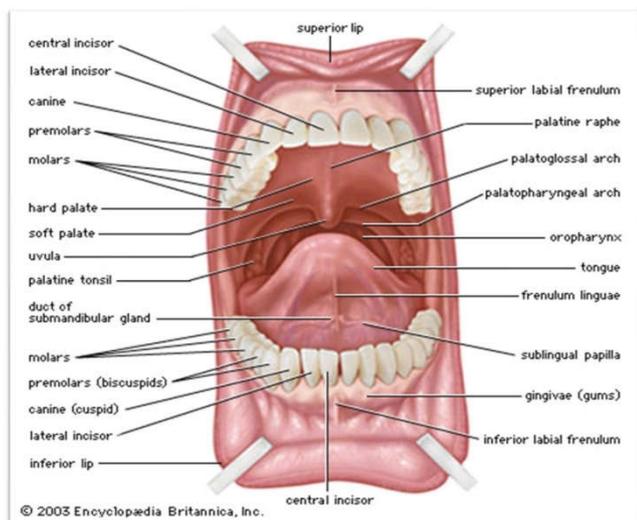


Figure-2: Structure of the oralcavity

MATERIALS AND METHODOLOGY

Pentazocine Gift sample from Micro laBP Pharmaceuticals Ltd., Goa. Carbopol 934p HPMC K4M Sodium CMC Mannitol PVP K-30 Magnesium stearate was obtained from Lupin Pharmaceuticals Ltd., Aurangabad

FORMULATION OF BUCCAL TABLETS OF PENTAZOCINE

Method for preparation of Buccal Tablets:

Tablets containing drug were prepared by direct compression technique. The drug and all other excipients, except Mg stearate were previously sieved through a 60 mesh were accurately mixed for 15 min by using a poly bag. The resulting mixture was mixed with Mg stearate and combined for mixing, up to 5 min. The mixer was compressed by using 10mm concave punches on sixteen station rotary tablet compression machine.

Table 1: Composition of Buccal Tablets of Pentazocine

| Formula | Drug | Carbopol 934p | HPMC C | Sodium CMC | PVP K 30 | Mannitol | Aspartame | Mg stearate |
|---------|------|---------------|--------|------------|----------|----------|-----------|-------------|
| BP1 | 10mg | 0 | 50 | -- | 4 mg | 20mg | 3mg | 2 mg |
| BP2 | 10mg | 3mg | 47 | -- | 4 mg | 20mg | 3mg | 2 mg |
| BP3 | 10mg | 6mg | 44 | -- | 4 mg | 20mg | 3mg | 2mg |
| BP4 | 10mg | 9mg | 38 | -- | 4 mg | 20mg | 3mg | 2 mg |
| BP5 | 10mg | 12mg | 35 | -- | 4 mg | 20mg | 3mg | 2 mg |
| BP6 | 10mg | | -- | -- | 4 mg | 20mg | 3mg | 2 mg |
| BP7 | 10mg | 0 | --- | 50mg | 4 mg | 20mg | 3mg | 2 mg |
| BP8 | 10mg | 3 | --- | 47mg | 4 mg | 20mg | 3mg | 2 mg |
| BP9 | 10mg | 6 | --- | 44mg | 4 mg | 20mg | 3mg | 2 mg |
| BP10 | 10mg | 9 | ---- | 41mg | 4 mg | 20mg | 3mg | 2 mg |
| BP11 | 10mg | 12 | ---- | 38 | 4 mg | 20mg | 3mg | 2 mg |
| BP12 | 10mg | 15 | ---- | 35 | 4 mg | 20mg | 3mg | 2 mg |

PREPARATION OF CALIBRATION CURVE OF PENTAZOCINE

Standard calibration curve of Pentazocine in methanol Standard solution:

Accurately weighed 100 mg of Pentazocine was dissolved in 100 ml of methanol to get a solution containing 1000 mcg/ml.⁵

Stock solution:

From the standard stock, a stock solution was prepared to give a concentration of 20 mcg/ml in methanol. Aliquots of 1, 2, 3, 4 and 5 ml of stock solution were pipette out into 10 ml volumetric flasks. The volume was made up to the mark with methanol. These dilutions give 2, 4, 6, 8 and 10 mcg/ml concentration of Pentazocine

respectively. The absorbance of prepared solution of Pentazocine in methanol was prepared at 210 nm in Shimadzu UV-1800 spectrophotometer against an appropriate blank (methanol).

Drug to polymer compatibility study's: IR spectrum of pure drug and other excipients were recorded using FTIR spectrophotometry.⁶

Pre-compression parameters

Angle of Repose: The angle of repose is the constant, three-dimension angle (relative to horizontal base) assumed by a cone like pile of material formed by any of several different methods. When the angle of repose exceeds 50degrees, the flow is rarely accepted for manufacturing purpose.⁷

Bulk Density: The bulk density was determined by transferring the accurately weighed sample of powder to the graduate cylinder. The initial volume and weight were noted. Ratio of weight of the sample was calculated by using the following formula.
Bulk Density =Mass /Bulk volume.

Tapped Density: Weighed powder sample was transferring to a graduated cylinder and was placed on the tap density apparatus, was operated for fixed number of taps (100). The tapped density was determined by the following formula.⁸

Tapped Density =Mass/Tapped volume.

Percentage compressibility: Based on the apparent bulk density and tapped density, the percentage compressibility of the bulk drug was determined by the following formula

%Compressibility=Tapped Density-Bulk density×100/ Tapped density.

Hauser's Ratio: It is measured by the tapped density to bulk density.
Hauser's Ratio= Tapped density/Bulk density

POST COMPRESSION PARAMETERS

Tablet thickness:

Randomly 5 tablets were taken from each formulation trial batch and their thickness was determined by using screw gauge.

Weight variation test:

20 tablets were randomly selected from each formulation trial batch and their average weight was calculated using digital balance. Individual weight of each tablet was also calculated using the same and compared with the average weight.⁹

Measurement of tablet hardness:

Hardness of 10 tablets was found using Monsanto hardness tester, mean and standard deviation were computed and reported. It is expressed in kg/cm²

Friability:

10 tablets were weighed and placed in Roche friabilator where the tablets were exposed to rolling and repeated shocks resulting from free falls within the apparatus. The Friabilator was operated at 25 rpm for 4 mins. After 100 revolutions, tablets were removed, deducted and weighed again. The friability was determined as the percentage loss in weight of the tablets.¹⁰

Swelling index:

The swelling rate of the tablet is evaluated by using pH 6.8 phosphate buffers. The initial weight of tablet is determined (W1). The tablet is placed in pH 6.8 phosphate buffer (6 ml) in a petridish placed in an incubator at 37 ± 1oC and the tablet is removed at different time

intervals (0.5, 1, 2, 3, 4, 5, 6, 7, 8 hr) blotted with filter paper and reweighted (W2).

% Swelling index = [(W2-W1)/W1] x100.

Surface pH:

The surface pH of the tablets was determined in order to investigate the possibility of any side effects on the oral cavity. As acidic or alkaline pH is found to cause irritation to the buccal mucosa, hence attempt was made to keep the surface pH close to the neutral pH. A combined glass electrode is used for this purpose. Buccoadhesive tablets were left to swell for 2 hr on the surface of 1 ml of distilled water (pH 6.8±0.05) at room temperature. The surface pH was measured by means of electrode by bringing it into contact with the tablet surface and allowing equilibrating for 1 min.

Bio adhesive force:

The apparatus used for testing bioadhesion was assembled in the laboratory. Bioadhesive strength of the buccal tablets was measured on the "Modified Physical Balance Method" employing the method described by Gupta et al using bovine cheek pouch as model mucosal membrane. The method uses sheep buccal membrane as the model mucosal membrane.

A double beam physical balance was taken. The left pan was removed. To left arm of a balance, a thick thread of suitable length was hanged. To the bottom side of thread a glass stopper with uniform surface was tied. A clean glass mortar was placed below hanging glass stopper. In this, mortar was placed on a clean 500 ml glass beaker, within which another glass beaker of 50 ml capacity in inverted position was placed and weighed with 50 gm to prevent floating. The pan control system involves placing thermometer in 500 ml beaker and intermittently adding hot water in outer mortar filled

Method:

The balance adjusted as described above was used for the study. The bovine cheek pouch excised and washed was tied tightly with mucosal side upward using the thread over the base of inverted 50 ml glass beaker. This beaker suitably weighted was lowered into 500 ml beaker, which was then filled with isotonic phosphate buffer (pH 6.8) kept at 37oC such that, the buffer reaches the surface of mucosal membrane & keeps it moist. This was then kept below left hand side of balance. The buccal tablet was then stuck to glass stopper through its backing membrane using an adhesive (feviquick). The 5gm on right hand side is removed. This causes application of 5 gm of pressure on buccal tablet overlying moist mucosa. The balance was kept in this position for 3 min and then slowly weights were increased on right pan, till tablet separates from mucosal membrane. The total weight on right pan minus 5 gm gives the force required to separate tablet from mucosa. This gives bioadhesive strength in grams. The mean value of three trials was taken for each set of formulations. After each measurement, the tissue was gently and thoroughly washed with isotonic phosphate buffer and left for 5 min before reading a new tablet of same formulation to get reproducible multiple results for the formulation.

Bio adhesive

In vitro drug release

This is studied by using the USP XIII dissolution test apparatus (Electro Lab, TDT-08L) by using rotating basket at 37 0.5°C at 100 rpm. Tablet is added to 200 ml of phosphate buffer of 6.8 pH. Samples are withdrawn at specified time intervals (0.5, 1, 2, 3, 4, 5, 6, 7, 8 hr) and replaced with fresh dissolution medium

(phosphate buffer pH 6.8). The amount of drug released is determined spectrophotometrically at 255 nm. The release rate study will be carried out for 8 hr.

Stability studies

Accelerated stability studies were performed at a temperature of $40 \pm 2^{\circ}\text{C}$ / $75 \pm 5\%$ RH over a period of three months (90 days) on the promising buccal tablets of Pentazocine. Sufficient number of tablets (15) were packed in amber colored rubber Stoppard vials and kept in stability chamber maintained at $40 \pm 2^{\circ}\text{C}$ / $75 \pm 5\%$ RH. Samples were taken at one month interval for drug content estimation. At the end of three month period, dissolution test was also performed to determine the drug release profiles.

RESULT AND DISSCUSSION

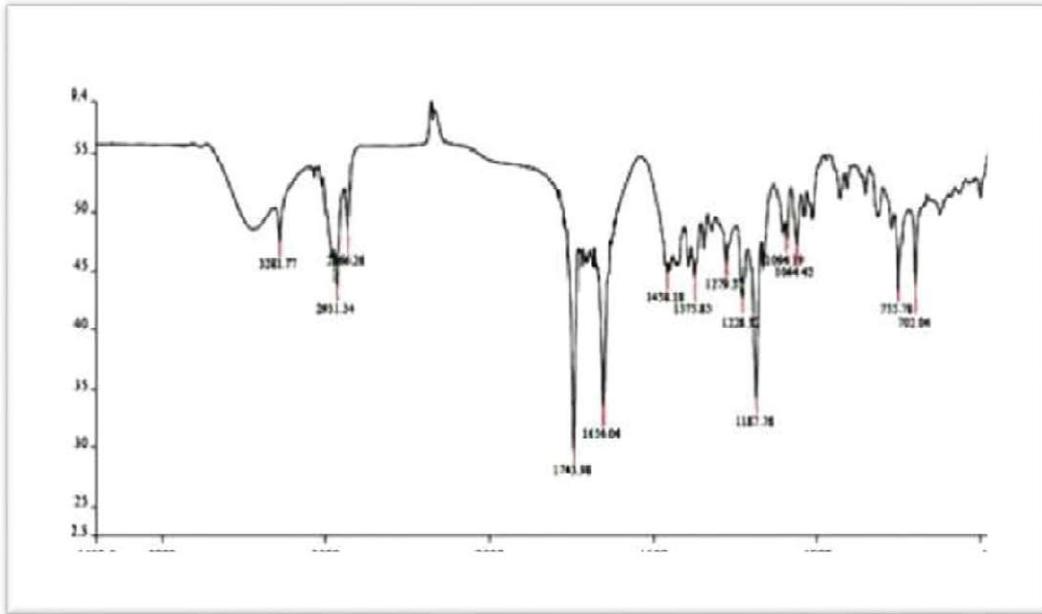


Fig No 3: FTIR spectra of pure drug

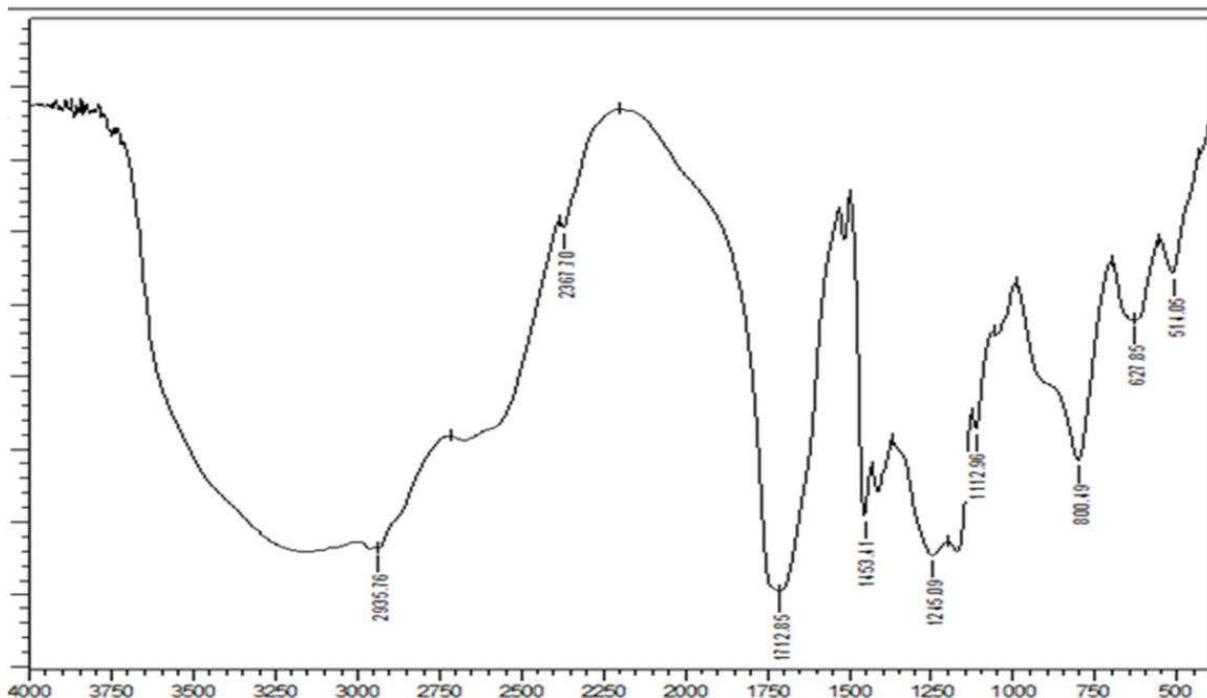


Fig No 4: FTIR spectra of pure drug and excipients.

Table No.5 Data for pre-compression parameters.

| Formulations | Angle of repose Θ | Bulk Density (g/cc) | Tapped Density (g/cc) | % Carr's index | Hausner's Ratio % |
|--------------|--------------------------|---------------------|-----------------------|----------------|-------------------|
| BP1 | 21.5± 0.270 | 0.481±1.295 | 0.509±0.915 | 4.98±1.759 | 1.05±0.656 |
| BP2 | 22.61±0.813 | 0.484±0.48 | 0.512±0.974 | 5.46±1.245 | 1.057±0.128 |
| BP3 | 20.91±0.270 | 0.490±1.295 | 0.509±0.915 | 3.16±1.759 | 1.03±0.956 |
| BP4 | 21.51±0.270 | 0.479±1.295 | 0.506±0.915 | 5.4±1.759 | 1.057±0.056 |
| BP5 | 23.22±0.257 | 0.568±0.421 | 0.625±0.730 | 9.12±1.350 | 1.10±0.164 |
| BP6 | 23.21±0.270 | 0.501±1.295 | 0.60±0.915 | 16.6±1.759 | 1.2±0.556 |
| BP7 | 22.22±0.270 | 0.512±1.275 | 0.610±0.912 | 16.68±1.759 | 1.17±0.520 |
| BP8 | 23.14±0.270 | 0.449±1.230 | 0.540±0.315 | 7.58±1.650 | 1.19±0.530 |
| BP9 | 21.23±0.270 | 0.512±1.394 | 0.622±0.615 | 17.68±1.732 | 1.08±0.556 |
| BP10 | 23.23±0.270 | 0.533±1.394 | 0.628±0.615 | 17.75±1.732 | 1.77±0.556 |
| BP11 | 24.23±0.270 | 0.532±1.394 | 0.639±0.615 | 17.42±1.730 | 1.22±0.76 |
| BP12 | 25.21±0.27 | 0.52±1.295 | 0.62±0.915 | 16.4±1.750 | 1.23±0.575 |

Table No.6 Data for Post -Compression Parameters

| Formulation | Mean Surface P ^H | Mean Hardness (Kg/cm ²) | Friability (%) | Mean Thickness (mm) | Mean Uniformity of Content (%) | Mean swelling index after 9 hrs | Mean Mucoadhesive strength(g) |
|-------------|-----------------------------|-------------------------------------|----------------|---------------------|--------------------------------|---------------------------------|-------------------------------|
| BP1 | 5.87±1.31 | 4.40±0.10 | 0.90±0.13 | 2.80±0.08 | 99.08±0.6 | 35.19±0.05 | 6.89±0.13 |
| BP2 | 5.87±1.23 | 4.90±0.10 | 0.88±0.08 | 2.87±0.12 | 98.15±2.98 | 42.48±0.59 | 8.42±0.11 |
| BP3 | 5.35±1.09 | 4.13±0.15 | 0.89±9 | 2.83±0.6 | 99.02±4.98 | 56.26±0.97 | 7.98±0.23 |
| BP4 | 5.87±1.31 | 4.40±0.10 | 0.56±0.65 | 2.90±0.90 | 99.23±0.34 | 62.98±0.87 | 9.02±0.03 |
| BP5 | 6.12±1.30 | 4.60±0.10 | 0.99±0.48 | 2.92±0.122 | 98.09±0.67 | 79.32±0.67 | 9.20±0.12 |
| BP6 | 6.23±1.24 | 4.47±0.11 | 0.78±0.98 | 2.88±0.89 | 101.75±0.67 | 87.25±0.75 | 9.24±0.14 |
| BP7 | 6.65±1.65 | 3.23±0.23 | 0.87±0.32 | 2.93±0.13 | 99.13±0.12 | 32.62±0.98 | 7.74±0.23 |
| BP8 | 5.31±0.31 | 3.93±0.12 | 0.89±0.54 | 2.96±0.89 | 98.73±0.65 | 39.55±0.87 | 8.08±0.43 |
| BP9 | 5.11±1.09 | 2.8±0.9 | 0.24±0.76 | 2.97±0.09 | 97.40±0.12 | 51.83±0.84 | 8.22±0.19 |
| BP10 | 6.87±1.24 | 2.76±0.9 | 0.76±0.87 | 2.94±0.12 | 99.51±0.81 | 69.04±0.84 | 9.10±0.19 |
| BP11 | 5.94±1.65 | 2.94±0.12 | 0.77±0.67 | 2.94±0.6 | 102.57±2.67 | 71.92±0.84 | 9.00±0.15 |
| BP12 | 6.09±1.31 | 2.95±0.13 | 0.67±0.8 | 2.95±0.13 | 101.45±0.97 | 73.12±3.84 | 8.09±0.10 |

Table no7: Invitrodrug release data of formulations BP1, BP2 and BP3

| Time hrs | Square root of time | Log time | Cumulative percent drug release | | | Log cumulative percent drug release | | | Cumulative percent drug remaining | | | Log percent drug remaining | | |
|----------|---------------------|----------|---------------------------------|------------|------------|-------------------------------------|-------|-------|-----------------------------------|-------|-------|----------------------------|-------|-------|
| | | | BP1 | BP2 | BP3 | BP1 | BP2 | BP3 | BP1 | BP2 | BP3 | BP1 | BP2 | BP3 |
| 0.5 | 0.7071 | -- | 19.76±2.90 | 17.56±1.09 | 16.57±2.16 | 1.295 | 1.244 | 1.219 | 80.24 | 82.44 | 83.43 | 1.904 | 1.916 | 1.921 |
| 1 | 1.0000 | 0.0000 | 27.36±2.99 | 24.16±0.88 | 21.93±0.88 | 1.437 | 1.383 | 1.341 | 72.64 | 75.84 | 78.07 | 1.861 | 1.879 | 1.892 |
| 2 | 1.4142 | 0.3010 | 34.35±2.09 | 31.35±0.98 | 28.66±.66 | 1.535 | 1.496 | 1.457 | 65.65 | 68.65 | 71.34 | 1.817 | 1.836 | 1.853 |
| 3 | 1.7320 | 0.4771 | 39.76±2.09 | 35.09±0.67 | 31.23±0.56 | 1.599 | 1.545 | 1.494 | 60.24 | 64.91 | 68.77 | 1.779 | 1.812 | 1.837 |
| 4 | 2.0000 | 0.6021 | 45.12±2.45 | 40.46±1.45 | 38.45±0.66 | 1.654 | 1.607 | 1.584 | 54.88 | 59.54 | 61.55 | 1.739 | 1.774 | 1.789 |
| 5 | 2.2360 | 0.6990 | 53.46±0.13 | 48.44±2.22 | 42.78±0.65 | 1.728 | 1.685 | 1.631 | 46.54 | 51.56 | 57.22 | 1.667 | 1.712 | 1.757 |
| 6 | 2.4494 | 0.7782 | 61.67±1.24 | 56.09±0.67 | 49.09±0.57 | 1.790 | 1.748 | 1.690 | 38.33 | 43.91 | 50.91 | 1.583 | 1.642 | 1.706 |
| 7 | 2.6457 | 0.8451 | 68.98±2.09 | 62.77±0.56 | 56.12±0.66 | 1.838 | 1.797 | 1.749 | 31.02 | 37.23 | 43.88 | 1.491 | 1.570 | 1.642 |
| 8 | 2.8284 | 0.9093 | 74.76±1.11 | 69.89±0.56 | 63.9±0.55 | 1.873 | 1.844 | 1.805 | 25.24 | 30.11 | 36.1 | 1.402 | 1.478 | 1.557 |

TableNo-8: *In vitro* drug release data of formulations BP4, BP5 and BP6

| Time hrs | Square root of time | Log time | Cumulative percent drug release | | | Log cumulative percent drug release | | | Cumulative percent drug remaining | | | Log percent drug remaining | | |
|----------|---------------------|----------|---------------------------------|------------|------------|-------------------------------------|-------|-------|-----------------------------------|-------|-------|----------------------------|-------|-------|
| | | | BP4 | BP5 | BP6 | BP4 | BP5 | BP6 | BP4 | BP5 | BP6 | BP4 | BP5 | BP6 |
| 0.5 | 0.7071 | -- | 14.57±0.89 | 13.09±0.09 | 11.02±0.98 | 1.160 | 1.116 | 1.042 | 85.43 | 86.91 | 88.98 | 1.936 | 1.939 | 1.949 |
| 1 | 1.0000 | 0.0000 | 19.24±0.11 | 17.76±0.76 | 16.86±0.54 | 1.284 | 1.249 | 1.226 | 80.76 | 82.24 | 83.14 | 1.907 | 1.915 | 1.919 |
| 2 | 1.4142 | 0.3010 | 24.56±0.34 | 21.09±0.67 | 19.56±0.65 | 1.390 | 1.324 | 1.291 | 75.44 | 78.91 | 80.44 | 1.877 | 1.897 | 1.905 |
| 3 | 1.7320 | 0.4771 | 28.98±0.45 | 26.34±0.98 | 25.67±0.89 | 1.462 | 1.420 | 1.409 | 71.02 | 73.66 | 74.33 | 1.851 | 1.867 | 1.871 |
| 4 | 2.0000 | 0.6021 | 34.78±0.98 | 32.89±0.56 | 30.68±0.33 | 1.541 | 1.517 | 1.486 | 65.22 | 67.11 | 69.32 | 1.814 | 1.826 | 1.840 |
| 5 | 2.2360 | 0.6990 | 40.22±0.45 | 37.02±0.76 | 36.86±2.09 | 1.604 | 1.568 | 1.566 | 59.78 | 62.98 | 63.14 | 1.776 | 1.799 | 1.800 |
| 6 | 2.4494 | 0.7782 | 46.8±0.98 | 44.98±0.32 | 43.78±1.09 | 1.670 | 1.653 | 1.641 | 53.2 | 55.02 | 56.22 | 1.725 | 1.740 | 1.749 |
| 7 | 2.6457 | 0.8451 | 53.86±0.98 | 51.67±0.11 | 49.13±0.21 | 1.731 | 1.713 | 1.691 | 46.14 | 48.33 | 50.87 | 1.664 | 1.684 | 1.706 |
| 8 | 2.8284 | 0.9093 | 60.34±0.09 | 57.09±0.89 | 55.45±0.22 | 1.780 | 1.756 | 1.743 | 39.66 | 42.91 | 44.55 | 1.598 | 1.632 | 1.648 |

Table No 9: *In vitro* drug release data of formulations BP7, BP8 and BP9

| Time hrs | Square root of time | Log time | Cumulative percent drug release | | | Log cumulative percent drug release | | | Cumulative percent drug remaining | | | Log percent drug remaining | | |
|----------|---------------------|----------|---------------------------------|------------|------------|-------------------------------------|-------|-------|-----------------------------------|-------|-------|----------------------------|-------|-------|
| | | | BP7 | BP8 | BP9 | BP7 | BP8 | BP9 | BP7 | BP8 | BP9 | BP7 | BP8 | BP9 |
| 0.5 | 0.7071 | -- | 23.35±1.09 | 21.46±2.81 | 19.56±1.09 | 1.368 | 1.331 | 1.291 | 76.65 | 78.54 | 80.44 | 1.884 | 1.895 | 1.905 |
| 1 | 1.0000 | 0.0000 | 31.35±0.99 | 29.44±1.56 | 27.32±0.67 | 1.496 | 1.468 | 1.436 | 68.65 | 70.56 | 72.68 | 1.836 | 1.848 | 1.861 |
| 2 | 1.4142 | 0.3010 | 39.98±0.67 | 36.09±0.98 | 32.06±0.44 | 1.601 | 1.557 | 1.505 | 60.02 | 63.91 | 67.94 | 1.778 | 1.805 | 1.832 |
| 3 | 1.7320 | 0.4771 | 48.76±0.34 | 42.67±0.56 | 38.21±0.67 | 1.688 | 1.630 | 1.582 | 51.24 | 57.33 | 61.79 | 1.709 | 1.758 | 1.790 |
| 4 | 2.0000 | 0.6021 | 56.12±0.65 | 52.11±0.89 | 46.92±0.12 | 1.749 | 1.716 | 1.671 | 43.88 | 47.89 | 53.08 | 1.642 | 1.680 | 1.724 |
| 5 | 2.2360 | 0.6990 | 66.45±0.11 | 60.54±1.56 | 56.23±0.01 | 1.822 | 1.782 | 1.749 | 33.55 | 39.46 | 43.77 | 1.525 | 1.596 | 1.641 |
| 6 | 2.4494 | 0.7782 | 74.66±0.45 | 68.34±2.00 | 62.87±1.25 | 1.873 | 1.834 | 1.798 | 25.34 | 31.66 | 37.13 | 1.403 | 1.500 | 1.569 |
| 7 | 2.6457 | 0.8451 | 81.69±0.56 | 76.76±1.34 | 70.01±0.46 | 1.912 | 1.885 | 1.845 | 18.31 | 23.24 | 29.99 | 1.262 | 1.366 | 1.476 |
| 8 | 2.8284 | 0.9093 | 89.77±0.98 | 82.87±1.45 | 78.35±0.45 | 1.953 | 1.918 | 1.894 | 10.23 | 17.13 | 21.65 | 1.009 | 1.233 | 1.335 |

Table-10: *In vitro* drug release data of formulations BP10, BP11 and BP12

| Time hrs | Square root of time | Log time | Cumulative percent drug release | | | Log cumulative percent drug release | | | Cumulative percent drug remaining | | | Log percent drug remaining | | |
|----------|---------------------|----------|---------------------------------|------------|------------|-------------------------------------|-------|-------|-----------------------------------|-------|-------|----------------------------|-------|-------|
| | | | BP10 | BP11 | BP12 | BP10 | BP11 | BP12 | BP10 | BP11 | BP12 | BP10 | BP11 | BP12 |
| 0.5 | 0.7071 | -- | 18.98±0.98 | 16.46±0.45 | 14.00±0.87 | 1.278 | 1.216 | 1.146 | 81.02 | 83.54 | 86.01 | 1.908 | 1.921 | 1.934 |
| 1 | 1.0000 | 0.0000 | 24.86±0.00 | 21.09±0.44 | 20.01±0.76 | 1.395 | 1.324 | 1.301 | 75.14 | 78.91 | 79.99 | 1.875 | 1.897 | 1.903 |
| 2 | 1.4142 | 0.3010 | 29.68±0.24 | 26.07±0.56 | 23.89±0.54 | 1.472 | 1.416 | 1.378 | 70.32 | 73.93 | 76.11 | 1.847 | 1.868 | 1.881 |
| 3 | 1.7320 | 0.4771 | 35.08±0.34 | 33.32±0.33 | 29.65±0.34 | 1.549 | 1.522 | 1.472 | 64.92 | 66.68 | 70.35 | 1.812 | 1.823 | 1.847 |
| 4 | 2.0000 | 0.6021 | 40.65±0.45 | 39.01±0.56 | 34.09±0.32 | 1.609 | 1.591 | 1.532 | 59.35 | 60.99 | 65.91 | 1.773 | 1.785 | 1.818 |
| 5 | 2.2360 | 0.6990 | 48.09±0.67 | 42.56±0.78 | 41.43±0.09 | 1.682 | 1.629 | 1.617 | 51.91 | 57.44 | 58.57 | 1.715 | 1.759 | 1.767 |
| 6 | 2.4494 | 0.7782 | 57.87±0.56 | 52.09±0.89 | 49.44±0.65 | 1.762 | 1.716 | 1.694 | 42.13 | 47.91 | 50.56 | 1.624 | 1.680 | 1.703 |
| 7 | 2.6457 | 0.8451 | 64.54±0.67 | 60.13±0.32 | 57.08±0.05 | 1.809 | 1.779 | 1.756 | 35.46 | 39.87 | 42.92 | 1.549 | 1.600 | 1.634 |
| 8 | 2.8284 | 0.9093 | 72.67±0.56 | 68.00±0.53 | 65.04±0.42 | 1.861 | 1.832 | 1.813 | 27.33 | 32.00 | 34.96 | 1.433 | 1.505 | 1.543 |

CONCLUSION

Mucoadhesive buccal tablets of Pentazocine can be prepared by direct compression method using HPMC K4M and Sodium CMC along with carbopol 934p as mucoadhesive polymers in different ratios.

All the prepared tablet formulations were found to be good without capping and chipping. As the amount of polymer in the tablets increases, the drug release rate decreases, whereas swelling index and mucoadhesive strength increases.

In all the tablet formulation, 3% PVP-K30 used as binder which showed acceptable hardness of prepared tablets. *In vitro* residence test for mucoadhesion indicated good mucoadhesive property of the prepared tablets. The promising formulation BP1 have displayed good water absorption, which indicates the prepared tablets showed better swelling ability in presence of little amount of water.

All the designed formulations of Pentazocine buccal tablets displayed zero order release kinetics and drug release follows non-Fickian diffusion mechanism. Short-term stability studies of the promising formulation (BP1) indicated that there are no significant changes in drug content and dissolution parameter values after 3 months at $40 \pm 2^\circ \text{C} / 75 \pm 5\% \text{RH}$. IR spectroscopic studies indicated that there are no drug-excipient interactions. Among the 12 formulations, the formulations BP1 (containing Sodium CMC 33.33% of matrix layer along with 0% w/w of carbopol 934p of matrix layer) was found to be promising, which showed $t_{25\%}$, $t_{50\%}$ and $t_{70\%}$ values of 0.30, 3.12 and 5.24 h respectively and released 89.77% drug within 8h. The formulations have displayed good bioadhesion strength (7.70 g).

RECOMMENDATIONS

Pentazocine has low oral bioavailability (18-20%) and undergoes extensive first-pass metabolism, making buccal delivery an attractive route to overcome these limitations .

Pentazocine has shown good permeability across buccal cell culture models, suggesting its suitability for buccal drug delivery. Pentazocine's low molecular mass, suitable pKa values (8.5 and 10), and log P of 2.0 make it a good candidate for novel sustained-release drug delivery systems, including buccal tablets .

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