FORMULATION, DEVELOPMENT AND EVALUATION OF
BUCCOADHESIVE PATCH OF AN ANTIHYPERTENSIVE DRUG

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ABSTRACT
The present investigation highlights the novel trans-mucoadhesive patch of Valsartan, an Angiotensin II receptor antagonist used as an anti hypertensive agent. The mucoadhesive bilayered buccal patches comprising of a drug containing mucoadhesive layer and drug free backing membrane were fabricated by solvent casting technique. The mucoadhesive layer was composed of mixture of drug and sodium alginate along with HPMC K15 & SCMC in varying composition and backing layer was made of Ethyl Cellulose. The double layer structure design was expected to provide drug delivery in a unidirectional fashion to mucosa and avoid loss of drug due to wash out with saliva. The fabricated patches were evaluated for Physical Appearance, Thickness, Weight uniformity, Folding endurance, Swelling study, Surface pH, PMA, PML ,WVTR, Stability study in human simulated saliva, In-Vitro Residence Time, In-Vitro Buccoadhesive Strength, Drug Content Uniformity, In-Vitro Buccal Permeation, In-Vitro Drug Release Study. A combination of Sodium alginate, HPMC K15 and SCMC (8:1:1) using glycerol (15% by weight of polymer) as plasticizer gave promising results. More than 89% drug was released in 6 hrs in case of optimized formulated buccal patch. The optimized formulation showed ‘n’ value 0.6142 indicating that drug release followed anomalous transport mechanism and the best fit model was observed to be Peppas kosmeyer model (R² = 0.9321).

Keywords: Valsartan, HPMC K15, SCMC, Ethyl cellulose, buccal patch, backing membrane, buccoadhesive.

INTRODUCTION
Oral drug delivery system is considered to be the most preferred route amongst the various available routes of drug delivery. However oral route has certain disadvantages such as first pass metabolism and enzymatic degradation within G.I.T. The buccal route as an alternative to other routes of drug administration has many advantages such as direct entry of drug into systemic circulation, therefore avoiding first pass hepatic metabolism and gastrointestinal drug degradation. The buccal cavity is easily accessible for self medication hence it is safe and well accepted by patients. The ease of administration and termination of drug when required makes buccal route attractive for drug delivery [1-4].
Valsartan is a specific angiotensin II receptor antagonist. It is used in treatment of hypertension, congestive heart failure and left ventricular dysfunctioning. It is a BCS class II drug (poorly soluble and highly permeable). On oral administration it is only 10-35% bioavailable and also has short biological half life requiring the administration two to three times daily to maintain adequate plasma levels of drug. This necessitates the development of sustained delivery system which permits direct access of active constituent to systemic circulation thereby passing first pass metabolism. During the last few decades, mucoadhesive polymers received considerable attention as platforms for buccal drug delivery of drugs due to their ability to localize dosage form in the specific regions to enhance drug bioavailability. In previous literature, no attempt has been made to formulate Valsartan buccal patches using Sodium alginate along with HPMC K15 and SCMC as mucoadhesive polymers and Ethyl cellulose as backing layer. In the present investigation an attempt was made to formulate Valsartan buccal patch using such combinations to ensure sustained drug release for a prolong period of time with satisfactory mucoadhesive properties.

MATERIAL AND METHODS

Material

Valsartan was obtained as a gift sample from M/s. Ranbaxy Research laboratories, Gurgaon; Sodium alginate was procured from Loba Chemicals Ltd. Mumbai, India; Ethyl Cellulose and HPMC K15 received from CDH New Delhi, India and SCMC was procured from Arora & comp. New Delhi, India. The other chemicals used were of analytical grade from different suppliers.

Drug polymer compatibility studies by FTIR

Drug polymer compatibility studies were performed by Fourier Transform spectroscopy (FTIR) in order to confirm that the entrapment of drug within the polymeric system involves only the physical process and no interaction between the drug and polymer. FTIR absorption spectra of pure drug and all the polymers used like Sodium alginate, HPMC K15, SCMC and combination of drug and polymers were analyzed to show any significant interaction between drug and polymers.

Analytical methodology
A solution of Valsartan of desired concentration (20 µg/ml) was prepared in investigating solutions, scanned between 200nm to 400nm using Shimadzu UV-1700, double beam spectrophotometer keeping investigating solution as blank. The wavelength at which maximum absorbance occurred was selected as the absorption maxima (λ<sub>max</sub>). Standard calibration curve of Valsartan was drawn by plotting absorbance versus concentration which was further used for determination of concentration of unknown samples.

Preparation of backing membrane

For the preparation of backing membrane a glass petridish of 7.7 cm diameter was used as a casting surface. Backing membrane of ethyl cellulose was fabricated by slowly pouring a solution containing 500 mg of ethyl cellulose and 2% dibutyl phthalate in 10 ml ethanol to the glass petridish and drying in an oven at 45°C for 3 hrs.

Preparation of bilayered buccal patches

Seven different placebo buccal patches (trial) were prepared using different concentration of Sodium alginate, SCMC, HPMC K15 and Carbopol (alone or in combination )in a suitable solvent (water) by solvent casting technique, detailed composition is given in Table 1. Glycerol was used as plasticizer. The mixture was stirred for fifteen minutes. Then the mixture was poured into the petridish having backing membrane and kept overnight at 40°C in a hot air oven. Among the seven patches (trials) prepared two patches were selected based on their physical evaluation.

### Table 1: Trial buccal patch formulation for optimization

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
<th>T5</th>
<th>T6</th>
<th>T7</th>
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<td>800</td>
<td>800</td>
<td>800</td>
<td>800</td>
<td>800</td>
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<tr>
<td>Carbopol</td>
<td>-</td>
<td>200</td>
<td>-</td>
<td>-</td>
<td>100</td>
<td>-</td>
<td>100</td>
</tr>
<tr>
<td>SCMC</td>
<td>-</td>
<td>-</td>
<td>200</td>
<td>-</td>
<td>100</td>
<td>100</td>
<td>-</td>
</tr>
<tr>
<td>HPMC K15</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>200</td>
<td>-</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Glycerol</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
<td>15%</td>
</tr>
</tbody>
</table>
Formulation of Valsartan buccal patches

Determination of drug loading The amount of drug loaded in the patch was calculated on the basis of patch area. Drug was loaded after dissolving in 4 ml of alcohol. Drug solution was added to polymeric dispersion of buccal patches formulation with continuous stirring to get homogenous mixture.

\[
\text{Total area of petridish} = 46.54 \text{ cm}^2 \\
\text{Area of buccal patch} = 3.14 \text{ cm}^2 \\
\text{Drug require in } 3.14 \text{ cm}^2 \text{ of patch} = 40 \text{ mg} \\
\text{Total drug loaded} = 592.87 \text{ mg}
\]

Different formulations of buccal patches were designed and prepared by solvent casting technique; the composition of each formulation is presented in Table 2.

**Table 2: Composition of different buccal mucoadhesive patches containing Valsartan**

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Concentration of polymers (mg)</th>
<th>Plasticizer concentration</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Sodium alginate</td>
<td>SCM C</td>
</tr>
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<td>F1</td>
<td>700</td>
<td>300</td>
</tr>
<tr>
<td>F2</td>
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<td>F6</td>
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<td>150</td>
</tr>
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<td>F7</td>
<td>800</td>
<td>50</td>
</tr>
<tr>
<td>F8</td>
<td>900</td>
<td>50</td>
</tr>
</tbody>
</table>

Evaluation of Buccal Patches

- **Physical Appearance:** The patches were observed visually for their physical appearance such as colour and transparency.
- **Thickness:** Thickness of patch was measured using screw gauze with a least count of 0.01 mm at different spots of the patch. The thickness was also measured for three different patches of the same formulation and average was taken. Standard deviation was also calculated.
• **Weight Uniformity:** Three patches of same size (2 cm diameter) of each formulation were weighed individually on a single pan balance and average weight was calculated.

• **Folding Endurance:** Folding endurance of the patch was determined mechanically by repeatedly folding one patch at the same place till it broke, or up to 300 times manually.

• **Swelling Study:**
  
  Weight and area increase due to swelling were measured

  1. **Weight increase due to swelling:** Buccoadhesive patch were weighed individually (designed as \( W_1 \)) and placed separately in 2% agar gel plates, incubated at 37 ± 1 °C and examined for any physical change. At regular 1 hour time intervals until 3 hours, patches were removed from the gel plates and excess surface water was removed carefully using filter paper. The swollen patches were then reweighed (\( W_2 \)) and Swelling Index (SI) was calculated using following formula:

     \[
     SI = \frac{W_2 - W_1}{W_1}
     \]

  2. **Area increase due to swelling:** A drug loaded patch size of 2 cm dia. was cut and placed in 2% agar gel plates, incubated at 37 ± 1 °C. After 3 hours increase in diameter was noted and area was calculated. The % swelling was calculated using following formula:

     \[
     \%S = \frac{X_t - X_0}{X_0} \times 100
     \]

     Where \( X_t \) = area of swollen patch after time t 
     \( X_0 \) = area of patch at time 0

• **Surface pH:** The formulations were first wetted by adding 1 ml distilled water to its surface. The surface pH was then recorded by bringing a glass electrode near the surface of formulation and allowing it to equilibrate for 1 min. The average pH ± SD was determined for all formulation.
• Percentage Moisture Absorption: For the determination of PMA, three 2-cm diameter patches were cut out and weighed accurately then the patches were placed in a desiccator containing saturated solution of aluminium chloride, keeping the humidity inside the desiccator at, 79.5 %. After 3 days, the patches were removed, weighed and percentage moisture absorption was calculated. Average percentage moisture absorption of three patches was found.

\[
PMA = \frac{Final\ weight - initial\ weight}{Initial\ weight} \times 100
\]

• Percentage Moisture Loss (PML): Three 2-cm diameter patches were cut out and weighed accurately and then the patches were placed in a desiccator containing fused anhydrous calcium chloride. After 3 days, the patches were removed, weighed and percentage moisture absorption was calculated. Average percentage moisture loss of three patches was found.

\[
PML = \frac{Initial\ weight - Final\ weight}{Initial\ weight} \times 100
\]

Water Vapour Transmission Rate (WVTR): This test was performed using vials of equal diameter as transmission cells. These cells were washed thoroughly and dried in an oven. About 1 gm of calcium chloride was taken in the cell and patch measuring 2 cm diameter were fixed over the brim with the help of an adhesive. The cells were weighed accurately and initial weight was recorded and then kept in a closed desiccator containing saturated solutions of potassium chloride. The humidity inside the desiccator was set to be between 80 and 90 % RH. The cells were taken out and weighed after 1, 2, 3, 4, 5, 6 and 7 days. From the increase in weights, the amount of water vapour transmitted and the rate at which water vapour transmitted (Q) were calculated by using the formula:

\[
Q = \frac{W \times L}{s}
\]

Where W is water vapor transmitted in grams,
L is thickness of patch in centimeters,
Stability Studies in Simulated Human Saliva:
The stability study of buccal films was performed in simulated human saliva which was prepared by dissolving 2.38 gm of disodium hydrogen phosphate, 0.19 gm of potassium dihydrogen phosphate and 8 gm of NaCl in 1000 ml of distilled water. The patches were placed in separate petridish containing 5 ml of simulated human saliva and kept in a temperature controlled oven at 37±2°C for 6 hrs. At regular time intervals, the patches were examined for change in colour, shape, collapse and physical stability.

• **In-Vitro Residence Time**: The in-vitro residence time was determined using IP disintegration apparatus. The disintegration medium was 900 ml of pH 6.8 phosphate buffer maintained at 37±2°C. The segment of cellophene membrane each of 3 cm length, was glued to the inner side of glass beaker about 2.5 cm from the bottom. The mucoadhesive patch of each formulation was hydrated on the surface using pH 6.8 phosphate buffer and pasted to cellophene membrane by applying a light force with fingertip for 30 seconds. Then motor was allowed to move up and down at sirring rate of 50 rpm. The patch was completely immersed in buffer solution at the lowest point and was out at highest point. The time required for complete erosion or detachment of patch from cellophane membrane was recorded.

• **In-Vitro Buccoadhesive Strength**: The fabricated balance was used for bioadhesion study. The cellophene membrane was fixed to movable plateform. The mucoadhesive patch was fixed to stainless steel lamila using fevi-quick as adhesive. The exposed patch was moistened with 1 ml of isotonic phosphate buffer for 30 seconds for initial hydration and swelling. The plateform was then brought in contact with hydrated patch. A preload of 25 gms was placed over the stainless steel lamila for 5 minutes as initial pressure. Then weights were increased slowly on other pan till the patch detached from cellophane membrane. The weights required to detach patch from cellophane membrane was recored as buccoadhesive strength.
• **Drug Content Uniformity:** The patch of known weight (dimension 2 cm diameter) was extracted with 25 ml of distilled water by shaking for 3 hours, kept it for 24 hours and then shaken for 3 hours. The solution is suitably diluted with distilled water and absorbance was measured in UV spectrophotometer at 250 nm against distilled water as blank.

• **In-Vitro Buccal Permeation:** The in-vitro permeation study of Valsartan through cellophane membrane was performed using Franz diffusion cell. The cellophane membrane was soaked for 24 hrs in phosphate buffer. A specimen of Cellophane membrane was mounted between the donor and receptor compartment. The film was placed on the membrane and the compartments were clamped together. The donor compartment was filled with 1 ml of phosphate buffer pH 6.8. The receptor compartment was filled with isotonic phosphate buffer pH 7.4 maintained at temperature 37±0.2°C and hydrodynamics in receptor compartment were maintained by stirring magnetically at 50 rpm. Aliquots of 2 ml sample were withdrawn at predetermined time intervals and replaced with 2 ml fresh buffer solution to maintain sink condition. The sample were filtered and analysed by UV spectrophotometer at 250 nm.

• **In-Vitro Drug Release Study:** The USP XXIII dissolution apparatus (paddle over disk) was used to study in-vitro drug release from buccoadhesive patches. 250 ml of phosphate buffer pH 7.4 was used as dissolution media at 37±0.5°C and rotation speed of 50 rpm was maintained. One side of the buccal patch was attached to the watch glass and kept at the bottom of dissolution vessel. Aliquots of 5 ml sample were withdrawn at specified time intervals and replaced with fresh media each time to maintain the sink conditions. The samples were filtered through whatman filter paper and analysed at 250 nm by UV spectrophotometer. The model dependent parameters were calculated using BITS 1.12 Software.

• **Ex-vivo permeation studies**

  **Preparation of porcine buccal mucosa:** Buccal mucosa excised from goat cheek pouch was obtained within 2 hrs of its death from the slaughter house and immediately transported to the laboratory in phosphate buffer solution. The
buccal mucosa was separated from full thickness of tissue after immersion in distilled water and then in isotonic phosphate buffer, pH 6.8 at 37±1°C for 2 min. The fatty layers were removed by scalpel and buccal mucosa was isolated from underlying tissue. Finally, the mucosa was washed with isotonic phosphate buffer pH 6.8.

Permeability studies: For ex-vivo permeation studies, in the experimental protocol goat mucosa was used as a barrier membrane instead of cellophane membrane and the same procedure as above was followed. The samples were analyzed in UV spectrometer at 250 nm.

- **Characterization of release kinetics:** The in-vitro and ex-vivo release data were fitted into different release kinetics like zero order, First order, higuchi kinetics, Peppas kinetics and $R^2$ values were calculated.

- **Scanning electron microscopy (SEM):** Morphology of the prepared optimized Valsartan buccal patch was observed under scanning electron microscope. The sample was attached to the slab surface with double sided adhesive tape and the scanning electron photomicrographs were taken at different magnifications.

- **Short Term Stability Studies:** The Optimized patches were cut in 2 cm diameter and were wrapped individually in aluminium foil and placed in polybag. Then all the patches were charged in stability chamber at 40°C and 75% RH for a period of one month. The patch from each formulation was analysed for drug content and dissolution study at the end of the month.

RESULTS AND DISCUSSION

- **Drug polymer compatibility studies by FTIR:** FTIR spectra of Valsartan, Sodium alginate, HPMC K15, SCMC and the combination of drug and polymers showed no significant interaction between drug and polymer. The prepared Valsartan buccal patches were characterised based upon their physicochemical characteristics like surface pH, PMA, PML, Q, Swelling percentage, thickness, weight and drug content.

- **Analytical methodology:** The $\lambda_{max}$ of Valsartan in water was determined to be 250 nm.
Physical characteristics of patches: The patches were translucent, having good strength and visually surfaced. The drug and polymers distribution was uniform.

Thickness Uniformity of Patches: All the drug loaded patches have uniform thickness throughout. Standard deviation of the thickness of patches ranged between 0.457±0.051 to 0.744±0.009.

Weight uniformity of patches: All the drug loaded patches showed uniformity in weight. Standard deviation of the thickness of patches ranged between 0.181±0.005 to 0.284±0.015.

Folding endurance: Folding endurance was found to be greater than 300 times in case of all the formulations. This makes the system acceptable for movement of mouth, indicating good strength and elasticity. Folding endurance test results indicate that the patches would maintain integrity with buccal mucosa when applied.

Swelling studies: The swelling of the patches were observed in agar gel plates and shown in table. Swelling was more pronounced in patch F5 and F4 showed less swelling.

Surface pH: The observed surface pH of the formulation was found to be in the range of 6.52±0.030 to 6.81±0.001 the result showed that there is no significant difference in the surface pH of all the formulations and the pH range lies within the range of salivary pH, i.e. 6.5-6.8, thereby may not cause irritation to the site of administration.

PMA and PML of buccal patch: By checking the physical stability of the patch at high humid conditions and integrity of patch at dry conditions, the patches were evaluated for PMA and PML.

Water vapour transmission rate (Q): Water vapour transmission studies indicate that all the patches were permeable to water vapour. The amount of water vapour transmission through the patches followed zero order kinetics. The water vapour transmission values were less in case of F3 and more in case of F5.
Stability Studies in Simulated Human Saliva: The patches did not exhibit any significant changes in their colour, shape and had satisfactory physical stability in simulated human saliva.

In-vitro residence time: all formulations showed satisfactory mucoadhesive time. Formulation F5 showed maximum time while formulation F3 showed less mucoadhesive time.

Buccoadhesive strength: All the formulations showed good buccoadhesive strength. Among the formulations F5 showed maximum buccoadhesive strength while formulation F7 showed less buccoadhesive strength.

Drug content uniformity: The results of drug content uniformity are shown in Table 3. Drug content in all formulations were found to be uniform ranging from 89 ± 0.03 to 94.90 ± 0.02.

In-Vitro Buccal Permeation: This test showed that the drug is sufficiently permeable to buccal mucosa. Permeability was found to be highest in case of F5 and least in case of F3.
• **In-Vitro Drug Release Study:** Distinguishable differences were observed in the release of Valsartan in all formulations as shown in figure 3.

![In-vitro drug release](image)

**Figure 3:** Release plot of Valsartan buccal patches from F1-F8

• **Kinetics of drug release:** to investigate the release kinetics of drug release from optimized buccal patch, the release data was subjected to fit various kinetics models (such as zero order, first order, higuchi and Peppas model) by using software BITS-SOFT 1.12 and value of $r^2$, n and k were determined. The optimized formulation showed 'n' value 0.6142 indicating that drug release followed anomalous transport mechanism and the best fit model was observed to be Peppas kosmeyer model ($r^2 = 0.9321$).

• **Ex-vivo permeation study:** Ex-vivo Drug permeation study of optimized patch resulted in % cumulative drug permeation of 41.8 % at 6th hour. Hence it showed the permeability of drug through goat buccal mucosa.

![Ex-vivo permeation study](image)

**Figure 4:** Ex-vivo permeation study
• Scanning electron microscopy (SEM): The scanning electron photomicrographs were taken at different magnifications as shown in Figure 5 & 6. SEM Photograph showed smooth nonporous surface and uniform dispersion of drug in polymer matrix.

![SEM Photograph](image1.png)

**Figure 5: SEM photograph depicting Valsartan buccal patch at 1000x magnification**

![SEM Photograph](image2.png)

**Figure 6: SEM photograph depicting Valsartan buccal patch at 5000x magnification**

<table>
<thead>
<tr>
<th>Formulation code</th>
<th>Content uniformity</th>
<th>Surface pH±SD</th>
<th>PM A ±SD</th>
<th>PML (%age)</th>
<th>Folding endurance</th>
<th>Swelling Studies</th>
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<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>% weight increase</td>
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<tr>
<td>F1</td>
<td>92.67±0.06</td>
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<td>4.54</td>
<td>4.54</td>
<td>314</td>
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<td>6.79±0.004</td>
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<td>F8</td>
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<td>414</td>
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Insertion table with content from the text above.
Table 4: Mechanical Parameters of Valsartan Buccal Patch

<table>
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<tr>
<th>Formulation code</th>
<th>Buccoadhesive strength (gm)</th>
<th>Force of adhesion (N)</th>
<th>Bond strength (N/m²)</th>
<th>In-vitro residence time (minutes)</th>
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<td>67</td>
<td>0.656</td>
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DISCUSSION: Drug polymer interaction studies by FTIR show no significant interaction between drug and polymers. All the physicochemical characteristic evaluated show satisfactory results with good bioadhesive strength, in-vitro residence time, swelling index and Water vapors transmission rate. The prepared patches of all the formulation are able to sustain the release for 6 hrs. SEM photograph of optimized patch shows smooth, nonporous surface and uniform distribution of drug in polymer matrix system. The optimized formulation showed ‘n’ value 0.6142 indicating that drug release followed anomalous transport mechanism and the best fit model was observed to be Peppas kosmeyer model (r² = 0.9321). Ex-vivo Drug permeation study of optimized patch resulted in % cumulative drug permeation of 41.8% at 6th hour.

CONCLUSION

In the present study a successful attempt has been made to formulate Valsartan buccal patches using Sodium Alginate along with various hydrophilic and mucoadhesive polymers in various proportions and combinations to ensure sustained release for prolonged periods with satisfactory mucoadhesive properties. From the present investigation, it can be concluded that such patch of Valsartan may provide sustained delivery through buccal route, which can be good way to bypass the hepatic first pass metabolism.

REFERENCES


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