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Development and characterization of nitroglycerine buccal oral films for rapid drug delivery

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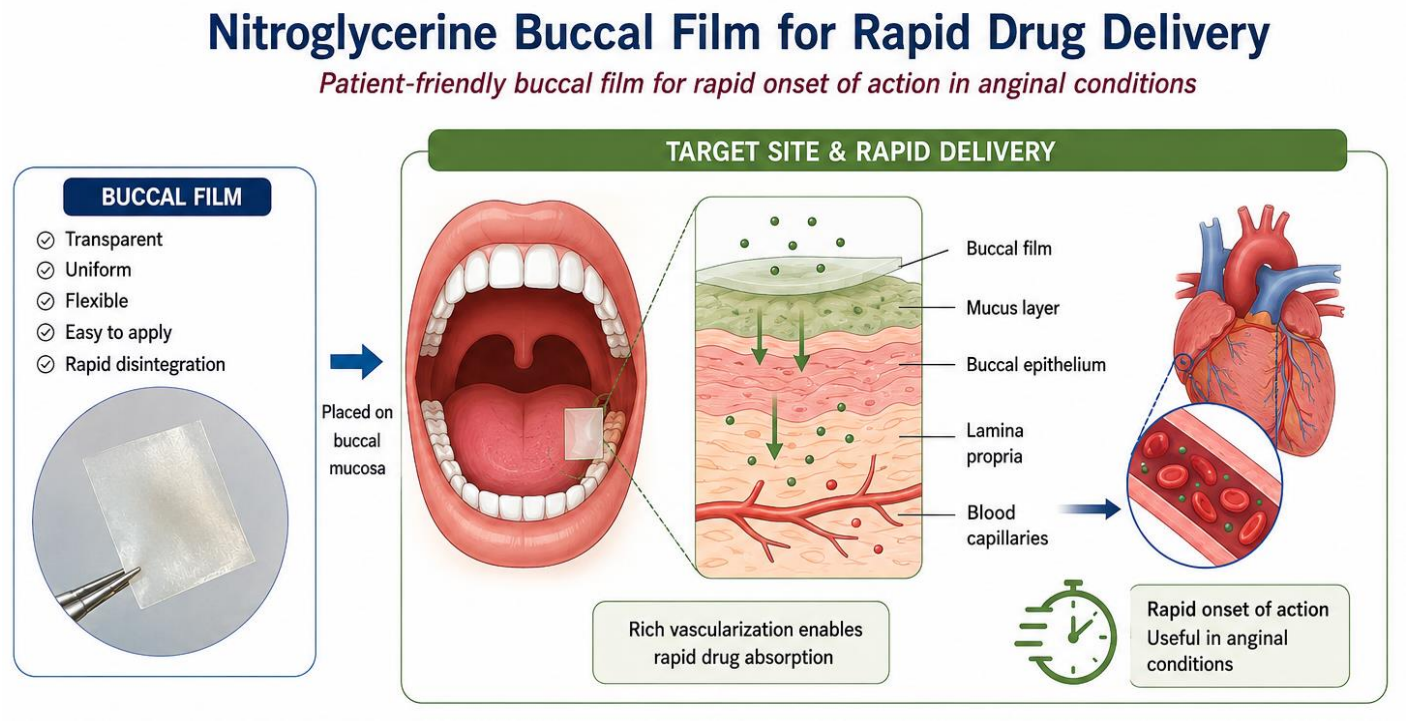
ABSTRACT

Buccal drug delivery is an attractive alternative to conventional oral dosage forms, which allows the administration of drugs through the vascularised mucosa of the oral cavity, potentially minimising exposure to gastrointestinal degradation and hepatic first-pass metabolism. In the present work, nitroglycerine-loaded buccal oral films were prepared by the solvent casting method and were evaluated for their physicochemical and mechanical properties. The main film-forming polymer used was hydroxypropyl methylcellulose (HPMC) 50 cps, and glycerol was used as a plasticiser. The prepared films were evaluated for appearance, weight variation, thickness, folding endurance, disintegration time and surface pH. The resulting films were homogeneous and transparent. Mean film weights for the formulations F1-F3 ranged from 71.6 to 73.0 mg, and the film thicknesses were from 0.45 to 0.63 mm.



The folding endurance values were observed to be around 23- 23.6, which indicates that the mechanical flexibility is sufficient. The films showed rapid disintegration with mean disintegration times of 21.0, 18.3 and 20.3 s for F1, F2 and F3, respectively. The surface pH was in a range of 6.5 to 6.6 that appeared to be compatible with the physiological environment of the buccal mucosa. Taken together, the results show that it is possible to prepare buccal films containing nitroglycerine that have acceptable physical and mechanical properties. Further optimization, drug-content analysis, dissolution profiling, stability assessment and in vivo evaluation are required before clinical or commercial development. Schematic representation of nitroglycerine buccal film placement on the buccal mucosa, rapid disintegration, mucosal absorption, and systemic drug delivery.

Keywords: Nitroglycerine, Buccal film, Oral thin film, Mucoadhesion, HPMC, Solvent casting, Drug delivery, Rapid disintegration.

INTRODUCTION

The development of patient-friendly drug-delivery systems has increasingly focused on alternative routes capable of improving administration, absorption and therapeutic convenience. Although oral administration remains the most widely used route for systemic drug delivery, several physiological and pharmaceutical barriers may limit its effectiveness, including gastrointestinal degradation, variable absorption and hepatic first-pass metabolism [1-3]. These limitations have stimulated interest in transmucosal delivery systems involving the nasal, rectal, vaginal, ocular, sublingual and buccal routes. The uploaded manuscript specifically emphasizes the potential of mucoadhesive systems to establish intimate contact between a polymeric delivery system and a mucosal surface, thereby supporting localised or systemic drug delivery [4].

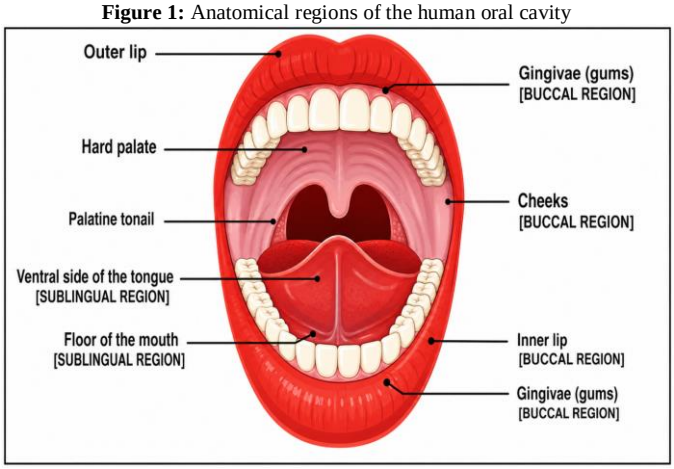
The buccal mucosa is particularly attractive for drug delivery because the oral cavity provides a readily accessible administration site with a relatively rich vascular supply. Buccal and sublingual delivery can therefore provide an alternative pathway for drugs for which conventional gastrointestinal administration may be less desirable. The source manuscript identifies sublingual delivery as particularly relevant for angina pectoris, because of its potential for rapid drug absorption and onset of action [5-7].

Buccal films are thin polymeric dosage forms that can be placed in the oral cavity and hydrate, disintegrate rapidly and release the drug contained. The high surface area and ease of administration may be advantageous as compared to conventional solid dosage forms. Moreover, buccal films may be useful for patients who experience difficulties swallowing conventional tablets. Also important are the ease of administration, rapid disintegration, portability and avoidance of swallowing, which are highlighted in the source manuscript [8-11].

Nitroglycerin is an established nitrate used in the management of anginal conditions. Conventional transmucosal administration is associated with rapid onset because the drug can be delivered through the oral mucosa. Development of a thin-film dosage form may provide an alternative patient-friendly presentation while retaining the fundamental advantages of transmucosal administration [12].

Mucoadhesion involves interaction between a polymeric delivery system and the mucus layer covering a biological surface as shown in Figure 1. The process can broadly be considered in terms of an initial contact stage followed by consolidation. During hydration, polymer chains can become mobile and interact with components of the mucus layer through hydrogen bonding, van der Waals interactions and polymer-chain interpenetration [13-15].

Figure 1: Anatomical regions of the human oral cavity



Schematic representation showing the major anatomical sites of the oral cavity, including the outer and inner lips, gingivae, hard palate, cheeks, palatine tonsils, ventral surface of the tongue, and floor of the mouth, with their corresponding buccal and sublingual regions.

In this study, nitroglycerine buccal films were prepared using the solvent-casting technique with HPMC 50 cps as the principal film-forming polymer. The prepared formulations were characterized using physicochemical and mechanical parameters, including appearance, thickness, weight variation, folding endurance, disintegration time and surface pH. The objective was to establish the feasibility of preparing a rapidly disintegrating nitroglycerine buccal film with acceptable physical characteristics.

MATERIALS AND METHODS

Chemicals

The formulation contained nitroglycerine, HPMC 50 cps, glycerol, ethanol, sweetening agent, colour, flavour and water. The quantities reported in the source manuscript were 1.42 mL nitroglycerine, 350 mg HPMC 50 cps, 1 mL glycerol and 1.5 mL ethanol, with the remaining components used in quantities sufficient for the intended formulation.

Preparation of buccal films

Buccal films were prepared by the solvent casting method. The formulation process involved the preparation of the polymeric film-forming solution, addition of the formulation components and casting to get a thin film. The solvent-casting method was chosen as it allows the preparation of thin polymeric matrices suitable for oral-film delivery. The source manuscript includes a schematic drawing of the preparation procedure.

Organoleptic assessment

The prepared films were visually examined for colour, odour, taste, clarity and overall appearance. The films of the tested formulations are described as transparent and homogeneous in the source manuscript.

Weight loss/gain

Films were cut from different locations of the cast film and weighed by an electronic balance. Mean weight was calculated from the individual weights.

Measuring thickness

The film thickness was measured with a calibrated micrometer/screw gauge. Measurements were taken at different locations or from single replicas, and the average value was calculated.

Folding endurance

The folding endurance was measured by repeatedly folding a film specimen at the same position until it broke. The number of repeated folds before breakage was taken as the index of film flexibility and mechanical strength.

Estimation of moisture

Films of 2 × 2 cm^2 were prepared and dried in a hot, dry oven at 50 °C for moisture-content evaluation. Initial and final weights were recorded and moisture loss calculated.

Surface pH measurement

Surface pH was determined to assess the potential compatibility of the films with the buccal mucosa. A 2 × 2 cm film sample was exposed to distilled water, and the pH was measured using a glass electrode. Measurements were performed in triplicate, and mean values were reported.

Disintegration testing

The disintegration time of the prepared films was determined using individual film specimens, with three measurements reported for each formulation. The mean and standard deviation were subsequently calculated.

RESULT

Physical appearance and mucoadhesive properties

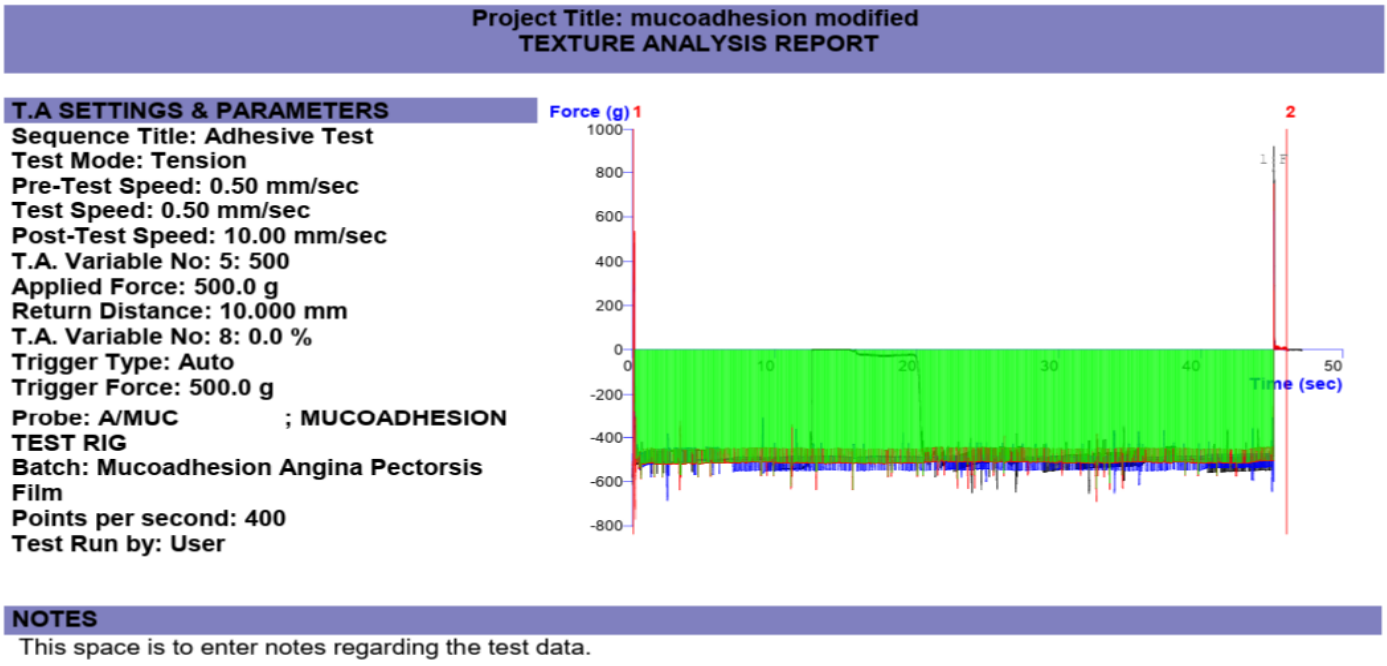
The prepared buccal-film formulations were visually examined for colour, clarity and overall physical appearance. All formulations designated F1-F5 were reported as transparent and homogeneous. The absence of visible heterogeneity indicates satisfactory distribution of the formulation components within the cast film matrix.

Table 1: Physical appearance of prepared buccal film formulations

Formulation	Appearance
F1	Transparent, homogeneous
F2	Transparent, homogeneous
F3	Transparent, homogeneous
F4	Transparent, homogeneous
F5	Transparent, homogeneous

The transparent and homogeneous appearance of the films suggests that the solvent-casting process produced visually uniform matrices under the preparation conditions used, and all the analyses are shown in Figure 2.

Figure 2: formulation mucoadhesive report



Film thickness

Thickness is an important characteristic of oral films because variation in thickness may influence dose uniformity, mechanical properties, hydration and drug release. Film thickness was determined using a screw-gauge/digital micrometre, with measurements obtained from multiple locations or replicas.

For F1, F2 and F3, the reported mean thickness values were 0.46 ± 0.01 mm, 0.54 ± 0.02 mm and 1.79 ± 0.03 mm, respectively, based on the values presented in the source table. However, the text that goes with it quotes a thickness range of 0.55-0.61 mm, which does not agree with the tabulated values. Therefore, the initial measurements should be checked with the laboratory notes before submission to a journal.

Table 2: Thickness of buccal-film formulations

Formulation	Replica 1 (mm)	Replica 2 (mm)	Replica 3 (mm)	Reported mean ± SD (mm)
F1	0.45	0.48	0.46	0.46 ± 0.01
F2	0.52	0.57	0.54	0.54 ± 0.02
F3	0.56	0.60	0.63	1.79 ± 0.03*

*The mean reported in the original manuscript is mathematically inconsistent with the three individual measurements and should be rechecked before publication.

Folding endurance

The folding endurance indicates the flexibility and mechanical strength of a polymeric film. In this work, the film specimens were folded repeatedly at the same location until they broke and the values were recorded.

The reported mean folding-endurance values were 23 ± 1 for F1, 23.6 ± 1.5 for F2 and 23 ± 1 for F3. Hence, the displayed formulations exhibited measurable flexibility and resistance to repeated folding.

Table 3: Folding endurance of buccal films

Formulation	Replica 1	Replica 2	Replica 3	Mean ± SD
F1	22	23	24	23 ± 1
F2	24	25	22	23.6 ± 1.5
F3	22	24	23	23 ± 1

The source manuscript also quotes a range of 25-26, which does not agree with the tabulated values. This discrepancy should be clarified with the original experimental data.

Weight variation

Uniformity of film weight is an important preliminary indication of consistency during casting and cutting. The average weights obtained for F1, F2 and F3 were 71.6 ± 1.52 mg, 73.0 ± 1.0 mg and 72.6 ± 1.1 mg, respectively.

Table 4: Weight variation of buccal-film formulations

Formulation	Replica 1 (mg)	Replica 2 (mg)	Replica 3 (mg)	Mean ± SD (mg)
F1	72	70	73	71.6 ± 1.52
F2	74	75	70	73.0 ± 1.0
F3	74	72	72	72.6 ± 1.1

The relatively small variation in mean film weight indicates reproducible film casting and cutting across the formulations tested.

Disintegration properties

Fast disintegration is of special importance for buccal and oral films which are intended to release the drug quickly. The measured disintegration times were 21.0 ± 1.732 s for F1, 18.3 ± 0.577 s for F2 and 20.3 ± 1.527 s for F3.

Table 5: Disintegration time of buccal films

Formulation	Replica 1 (s)	Replica 2 (s)	Replica 3 (s)	Mean ± SD (s)
F1	20	23	20	21.0 ± 1.732
F2	19	18	18	18.3 ± 0.577
F3	20	22	19	20.3 ± 1.527

Among the tested formulations, formulation F2 had the least average disintegration time. These results support the potential of the developed polymeric films for rapid disintegration after exposure to the oral environment.

Surface pH

Surface pH was studied, as a major deviation from the physiological environment of the buccal mucosa can cause discomfort or irritation. The measured surface pH values were close to neutrality, with mean values of 6.6 ± 0.81, 6.5 ± 0.12 and 6.6 ± 0.12 for F1, F2 and F3, respectively.

Table 6: Surface pH of buccal films

Formulation	Replica 1	Replica 2	Replica 3	Mean ± SD
F1	6.5	6.6	6.7	6.6 ± 0.81
F2	6.4	6.5	6.7	6.5 ± 0.12
F3	6.7	6.8	6.5	6.6 ± 0.12

The pH values close to neutral indicated that the prepared films were in a range suitable for further investigation of buccal application.

DISCUSSION

The present study shows the possibility of producing nitroglycerine-loaded buccal films by the solvent casting method. The development of thin polymeric dosage forms is particularly relevant for drugs requiring convenient administration and possibly rapid transmucosal delivery.

The main film-forming polymer was HPMC 50 cps, and glycerol was used as a plasticising component in the formulation. The preparation composition presented in the original manuscript also consisted of ethanol, water, sweetening agent, coloring and flavoring components.

The appearance of the formulations was good. All reported formulations were transparent and homogeneous. A uniform appearance is preferred, since visible phase separation or particulate aggregation may indicate poor compatibility of formulation components or inadequate mixing during preparation.

The thickness results showed significant differences between the formulations. Such differences may be due to variation in polymer concentration, casting conditions, solvent evaporation and film thickness across the casting surface. But before statistical interpretation of the raw experimental measurements, we should test

for a discrepancy between the individual thickness measurements and the reported mean for F3 in the original manuscript.

Endurance tests of folds showed that the films could be measured for flexibility. This property is important in handling, packaging and administration because a brittle film might fracture during removal from packaging or placement in the oral cavity. The raw data show that F1-F3 have similar folding-endurance values. However, the descriptive text needs to be corrected to align with the numerical table.

Weight variation was relatively low among F1-F3, indicating good reproducibility in film preparation and cutting. However, uniformity of weight does not guarantee uniformity of dose. A quantitative drug-content analysis by an appropriately validated analytical method would be required to demonstrate the uniform distribution of nitroglycerine within the films.

All three formulations tested disintegrated rapidly. The lowest mean disintegration time was recorded in F2 (18.3 s), whereas F1 and F3 showed mean values of 21.0 and 20.3 s, respectively. Rapid disintegration may be beneficial in case of oral film systems that are designed to provide rapid release of drug. However, disintegration time should not be confused with drug-release rate. A dedicated in vitro dissolution/release study is required to determine the relationship between film disintegration and nitroglycerine release.

The measured surface pH values were in the range of about 6.5-6.6. Buccal application is desired to maintain a near-neutral surface environment, since strongly acidic or alkaline formulations may cause irritation of the mucosa. The results therefore support further investigation of the formulations from a buccal compatibility perspective.

Overall, the physicochemical characterization indicates that the developed films possess several desirable preliminary characteristics. However, the current dataset does not establish drug-content uniformity, quantitative nitroglycerine release, permeation through buccal tissue, mucoadhesive strength, long-term stability, pharmacokinetic performance or clinical efficacy. These parameters should be addressed in subsequent studies.

CONCLUSION

Nitroglycerine-loaded buccal films were successfully prepared using the solvent-casting technique with HPMC 50 cps as the principal film-forming polymer. The prepared formulations exhibited a transparent and homogeneous physical appearance, acceptable preliminary mechanical characteristics, relatively consistent film weight, rapid disintegration and near-neutral surface pH.

The observed disintegration times of approximately 18-21 s and surface-pH values of approximately 6.5-6.6 indicate that the formulations possess characteristics suitable for further development as buccal film systems. However, the present study should be considered a formulation-development and preliminary characterization study rather than evidence of clinical efficacy.

Before consideration for publication in a high-impact journal, the study should be strengthened by quantitative drug-content determination, validated analytical methodology, in vitro dissolution/release kinetics, mucoadhesive-strength testing, ex vivo permeation studies, stability testing and appropriate statistical analysis. In addition, all discrepancies between reported numerical values and their corresponding tables should be resolved using the original laboratory data.

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