Research in Pharmacy and Health Sciences 2023,9(1):205-208. • https://doi.org/10.32464/RPHS.2023.v09i01.01 e-ISSN: 2455-5258

RESEARCH ARTICLE OPEN ACCESS

Formulation and Evaluation of Moxifloxacin Hydrochloride Buccal Film

Priyanka Gupta*, Ujjwal Nautiyal, Ramandeep Singh
Department of Pharmaceutics, HIP Paonta Sahib, HPTU, Hamirpur (H.P)

Received: 02 February, 2023
Accepted: 25 March, 2023

***Correspondence to:**
Priyanka Gupta
Email: priyanksgupta@gmail.com

Published by: OZZIE Publishers
Web: www.ozziepublishers.com

Abstract
As an antibiotic Several bacterial infections may be treated with Moxifloxacin hydrochloride. This medication belongs to the family of drugs known as quinolone antibiotics. It does its job by preventing germs from multiplying. In order to increase treatment effectiveness, Moxifloxacin hydrochloride mucoadhesive buccal films were developed for this research. Five different mucoadhesive Moxifloxacin hydrochloride buccal film formulations were created for the current investigation. As mucoadhesive polymers, Polyvinylpyrrolidone K-90 and hydroxypropyl methylcellulose were used as the main solvents. We examined the films' weight, thickness, surface pH, swelling index, homogeneity of the drug content, and folding toughness in *In-vitro* release and penetration investigations. Films from permeation studies demonstrated regulated release for over ten hours. It was discovered that the films containing 10 mg of hydroxypropyl methylcellulose and Moxifloxacin hydrochloride (0.04 percent), (Poly vinyl pyrrolidone 0.04 percent, 0.06 percent, 0.1 percent, and 0.3 percent, respectively) showed promising controlled drug release, good swelling, and a convenient residence time; they can therefore be selected for use in creating therapeutic buccal films.

KEY WORDS: Buccal film, Moxifloxacin, *in-vitro* studies, mucoadhesive, improving patience compliance.

1. INTRODUCTION

Buccal mucosa is one of the transmucosal routes with the best accessibility, the largest span of smooth muscles, and the least amount of mobility, making it ideal for administering retentive dose forms. Without passing through the liver, rich blood flow from the oral cavity enters the jugular vein[1]. Unlike conventional oral dosage forms, buccal muco-adhesive drug formulations remain in contact with the mucosa for a long time, enabling the medication to absorbed directly into the bloodstream via the oral mucosa and increasing bioavailability by decreasing the rate of gastrointestinal enzymatic degradation and the hepatic first pass effect[2]. The mouth cavity, which links the inside of the body to the outside world, is prone to a variety of diseases that must be treated locally, including herpes, canker sores, oral candidiasis, gingivitis, periodontal disease, and oral candidiasis[3]. There have been considerable advancements and adjustments made in the distribution of medications through innovative means of administration[4,5]. Drug delivery systems can be delivered by various routes such as oral, nasal, ocular, rectal and vaginal[6-8].

Buccal films are a relatively new dosage type for buccal delivery. They have grown in prominence as innovative and effective medication delivery methods that are both economical and have high patient compliance. Buccal films may be designed to stay put on the cheek and have systemic as well as local effects. When compared to buccal pills, buccal film may be more convenient because of its convenience and adaptability. The high bioavailability of buccal films is due to their capacity to bypass the liver's first pass metabolism and enter the systemic circulation through the internal jugular vein. These dose forms also offer greater patient compliance, are self-administrable, and are pharmacoeconomic[9-16]

2. MATERIAL AND METHODS

Moxifloxacin Hydrochloride, PVP K-90, propylene glycol, HPMC, sucrose and other chemicals used were of analytical grade.

Preparation of mucoadhesive buccal films

Using a solvent casting method, buccal films of moxifloxacin, formed using film-forming mucoadhesive polymers Hydrochloride, were created. Ten millilitres of distilled water were used to dissolve the measured amount of PVP. Polymer and distilled water were placed in a beaker and left alone for 5 minutes while being agitated to allow the

polymer to expand. After that, we added a single drop of propylene glycol to the polymer mixture. Simultaneously, 10 millilitres of distilled water with PVP as a solvent were added to a beaker containing a precise weight of moxifloxacin Hydrochloride , which was subsequently dissolved. The polymer was mixed with the medication solution, and then sucrose was added. An effective stir was achieved with the aid of a magnetic stirrer for the solution. A glass Petri dish was put on a level surface, and the whole solution was poured into it. The dish has an inverted funnel installed on top of it to slow down the rate of evaporation. For 12 hours, we allowed the polymeric solution of the medication to dry out in a Petri dish at room temperature. Once the films had dried on the Petri plate, any remaining flaws in them were inspected. They were vacuum-sealed in pouches and stored in desiccators until the assessment tests could be run. The purpose of seeing all of these brand-new films was to choose the one with the most desirable qualities**[**17,18].

3. CHARACTERIZATION

Physical appearance

Colour, clarity, texture, and uniformity were only some of the visual qualities of the buccal patch formulations that were evaluated.

Peel adhesion test

Films were dried in a 40°C oven for 12 hours before being peeled off a Petri dish. Therefore, films' peel ability, or their ability to be readily removed, was evaluated[19].

Thickness of film

The thickness of each film was measured using a dial gauge that had been calibrated for accuracy. In order to determine the average thickness of each film, it was placed between the anvil and presser foot of the dial gauge five times at various locations[20].

Weight variation

The weight variance was examined by contrasting the average 10 patches' weights from each batch to the weights of the individual patches[21].

Measurement of folding endurance

The hand-folding durability of the prepared films was measured by repeatedly folding the films at the same point until they broke. A film's ability to withstand repeated folding without ripping or splitting was determined by counting the number of times it could be folded in the same location without deterioration[22].

Content uniformity of films

A content uniformity test was conducted to guarantee that moxifloxacin hydrochloride was dispersed evenly across the film. After adding the film to the 200 mL of distilled water, we got the following: We used a temperature-controlled magnetic stirrer to keep a 250-mL beaker of buffer (20:80; phosphate buffer saline pH 7.4) at a constant 37°C. Over the course of three hours, 300 rpm were used to mix the medium. The filtered liquid was then evaluated after being pushed through a 0.45-micron membrane[23].

Measurement of surface pH

Three films of each formulation were put on top of the distilled water and allowed to expand for two hours in order to measure the surface pH[24].

Swelling studies

After establishing the film's primary weight (w1), samples were incubated at 37°C in distilled water. The films were removed every two to three hours until their weight stabilised, at which point the excess filter paper was used to remove water from the films after it had expanded on their surface (w2), which was remeasured, and the swelling index (SI) was computed[25].

In-vitro drug transport

Franz diffusion cells with a for the in vitro drug transport study, we utilised a receptor compartment, a donor compartment, a sampling port, and an outer jacket. The donor and receptor volumes remained constant at 3 and 5 millilitres, respectively. A Teflon-coated magnetic bead was placed at the bottom of the receptor compartment, and 500 ml of distilled water was added. The whole thing was placed on a magnetic stirrer. The constant temperature of 371^0C was achieved and maintained. The pig buccal mucosa was used to study the rate of penetration in more detail. An hour of equilibration in distilled water was used after it was attached to the Franz diffusion cell's receptor chamber's mouth. The donor compartment was re-equilibrated with 3 ml of distilled water. A holder was used to secure the assembly, and diffusion was performed for 2 hours. At regular intervals, a 0.3 ml sample was removed from fresh media and placed into the receptor compartment through the sampling port. Ultraviolet spectrophotometry at ʎmax 294 nm was used to examine the material that was withdrawn[26].

Formulation Polymer	**F1**	**F2**	**F3**	**F4**	**F5**
Drug	10%	10%	10%	10%	10%
PVP K-90	0.04%	0.06%	0.1%	0.3%	0.1%
HPMC	-	-	-	-	0.04%
Sucrose	4%	4%	4%	4%	4%
Propylene glycol	1-2 drop	1-2 drop	1-2 drop	1-2 drop	1-2 drop
Distilled water	2%	2%	2%	2%	2%

Table 1. Composition of mucoadhesive buccal films

4. RESULTS AND DISCUSSION

Buccal films of Moxifloxacin Hydrochloride were prepared with the use of mucoadhesive polymers such as PVP K-90 and HPMC. The prepared films were evaluated for different physicochemical tests such as weight variation, thickness, content uniformity, swelling index, surface pH, and in vitro drug release studies.

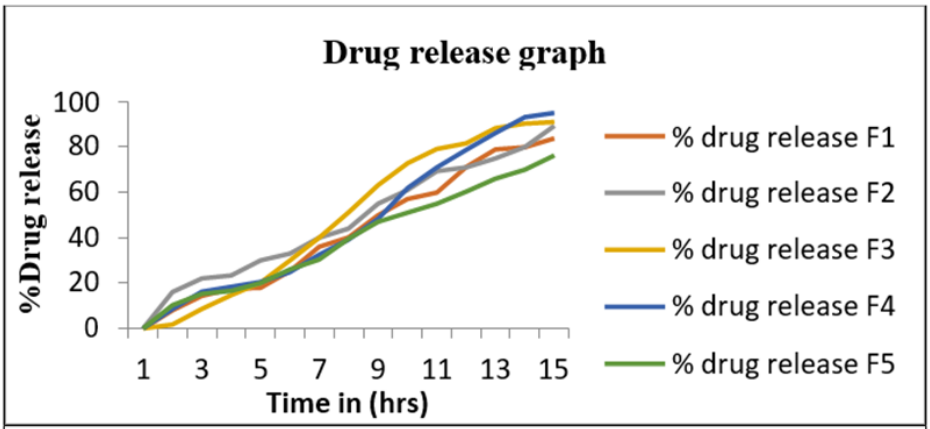
The physical appearance was found to be satisfactory in terms of opaqueness, smoothness, and uniformity. Peel ability was satisfactory after 12 hours of drying at 40°C in an oven; the films were easily peeled.

All the films showed uniform thickness throughout. The results showed that the folding endurance ranged from 3.5 to 4.122 seconds. It was determined that these values are optimal for revealing desirable film qualities.

The films' overall thickness was consistent. Observations revealed a film thickness ranging from 0.02±0.49 to 0.12±0.08 mm, with an average value of 0.173 mm. Various formulations were discovered to have weights ranging from 32.3 to 116.1 milligrams.

In order to prevent mucosal irritation and boost patient compliance, all formulations had to have a surface pH within 6.8 units of neutral. The content uniformity findings showed that the medication was spread out evenly, with a concentration of between 17.79 and 21.0 mg/cm^2. The swelling studies were found to be satisfactory, with phosphate buffer solution at pH 6.6 causing the films to swell. Comparative swelling tests across various formulations showed promising results.

The *in-vitro* drug release was found to be satisfactory. Phosphate buffer at pH 6.8 was used for in vitro release investigations of several formulations. Spectrophotometric analysis at 294 nm was used to calculate the drug concentration. The release profile of Moxifloxacin Hydrochloride films incorporating PVP, HPMC was significantly different. The percentage of total release after 10 hours was determined to be between 95.00 and 91.00. After 10 hours, the drug release from formulations F4>F3>F2>F1>F5 was determined to be 95.00>91.00>89.30>83.80>76.30.



Graph 1: Drug release graph of different formulation

Formulation code	Swelling index (2 h)	Content uniformity	Thickness (mm)	Weight variation	Folding endurance	Surface pH
F1	15.12±1.10	17.79±0.78	0.02±0.49	32.0±33.01	221.4±5.41	6.49±6.48
F2	19.00±1.09	18.00±0.12	0.13±0.22	38.0±0.00	220.5±1.31	6.55±6.54
F3	22.33±1.12	19.67±0.09	0.14±0.07	73.1±0.01	276.0±6.0	6.59±6.48
F4	26.35±1.23	20.00±0.09	0.41±0.01	112.2±0.02	168.5±3.62	6.71±6.70
F5	34.01±0.12	21.23±0.55	0.12±0.08	196.0±0.00	200±3.11	6.80±6.79

Table 2. Physical evaluation of mucoadhesive buccal films of moxifloxacin Hydrochloride

5. CONCLUSION

From the above study, we concluded that we can use buccal film of Moxifloxacin Hydrochloride for controlled release of drug for 12 hours, and thus it may be a better dosage form for old patients with sore throats and gum lining infections by giving them directly to the infected area.

REFERENCES

[1]. Anders R, Merkle HP. Evaluation of laminated muco-adhesive patches for buccal drug delivery. International Journal of Pharmaceutics. 1989 Feb 1;49(3):231-40.

[2]. Saurabh R, Malviya R, Sharma PK. Trends in buccal film: Formulation characteristics, recent studies and patents. Eur J Appl Sci. 2011;3:93-101.

[3]. Paderni C, Compilato D, Giannola LI, Campisi G. Oral local drug delivery and new perspectives in oral drug formulation. Oral surgery, oral medicine, oral pathology and oral radiology. 2012 Sep 1;114(3):e25-34.

[4]. Gondaliya D, Pundarikakshudu K. Studies in formulation and pharmacotechnical evaluation of

controlled release transdermal delivery system of bupropion. AAPS PharmSciTech. 2003 Mar;4:18-26.

[5]. Singh A, Sharma UK, Prajapati SK. A review on mucoadhesive buccal patches. International Journal of Research and Development in Pharmacy & Life Sciences. 2017 Jul 15;6(4):2654-60.

[6]. Salamat-Miller N, Chittchang M, Johnston TP. The use of mucoadhesive polymers in buccal drug delivery. Advanced drug delivery reviews. 2005 Nov 3;57(11):1666-91.

[7]. Gandhi RB, Robinson JR. Bioadhesion in drug delivery. Indian Journal of Pharmaceutical Sciences. 1988 May 1;50(3):145.

[8]. Boddupalli BM, Mohammed ZN, Nath RA, Banji D. Mucoadhesive drug delivery system: An overview. Journal of advanced pharmaceutical technology & research. 2010 Oct;1(4):381.

[9]. Lee JW, Park JH, Robinson JR. Bioadhesive-based dosage forms: The next generation. Journal of pharmaceutical sciences. 2000 Jul 1;89(7):850-66.

[10]. Veuillez F, Kalia YN, Jacques Y, Deshusses J, Buri P. Factors and strategies for improving buccal absorption of peptides. European journal of Pharmaceutics and Biopharmaceutics. 2001 Mar 1;51(2):93-109.

[11]. Parmar Harshad G, Janak Jain J, Tarun Patel K, Vishnu Patel M. Buccal Patches: A Technical Note. International Journal of Pharmaceutical Sciences Review and Research. 2012; 4(3):178-182.

[12]. Hoogstraate AJ, Cullander C, Senel S, Verhoef JC, Boddé HE, Junqinger HE. Diffusion rates and transport pathways of FITC-labelled model compounds through buccal epithelium. Journal of Controlled Release. 1994 Jan 1;28(1-3):274.

[13]. Kunte S, Tandale P. Fast dissolving strips: A novel approach for the delivery of verapamil. Journal of pharmacy and bioallied sciences. 2010 Oct;2(4):325.

[14]. Keshavarao KP, Mudit D, Gunashekara K, Anis S, Singh Mangla N, Ajay K. Formulation and evaluation of mouth dissolving film containing Rofecoxib. IRJP. 2011;2(3):273-8.

[15]. Gavaskar B, Kumar SV, Sharan G, Rao YM. Overview on fast dissolving films. International Journal of Pharmacy and Pharmaceutical Sciences. 2010;2(3):29-33.

[16]. Radhakisan UR, Chavan V, Tribhuvan N. Mouth dissolving film and their patent: An overview. International Research Journal of Pharmacy. 2012;3(9):39-42.

[17]. Semalty M, Semalty A, Kumar G. Formulation and characterization of mucoadhesive buccal films of glipizide. Indian journal of pharmaceutical sciences. 2008 Jan;70(1):43.

[18]. P. A. Insel, "Analgesic-Antipyretic and Anti-Inflammatory Agents and Drugs Employed in the Treatment of Gout," In: J. G. Hardman, L. E. Limbird, P. B. Molinoff, R. W. Ruddon and A. Goodman Gilman, Eds., Goodman and Gilman's the Pharmacological Basis of Therapeutics, 9th Edition, McGraw-Hill, New York, 1996, pp. 617657.

[19]. Sayed S, Ibrahim HK, Mohamed MI, El-Milligi MF. Fast-dissolving sublingual films of terbutaline sulfate: formulation and in vitro/in vivo evaluation. Molecular Pharmaceutics. 2013 Aug 5;10(8):2942-7.

[20]. Janßen EM, Schliephacke R, Breitenbach A, Breitkreutz J. Drug-printing by flexographic printing technology—A new manufacturing process for orodispersible films. International journal of pharmaceutics. 2013 Jan 30;441(1-2):818-25.

[21]. Panigrahi L, Pattnaik S, Ghosal SK. Design and Characterization of Mucoadhesive Buccal Patches of Dicofenac Sodium. Indian journal of pharmaceutical sciences. 2005;67(3):319.

[22]. Nafee NA, Ahemed F, Borale A. Preparation and evaluation of mucoadhesive patches for delivery of cetylpyridinium chloride (CPC). Acta Pharma. 2003;53:199-212.

[23]. Eouani C, Piccerelle P, Prinderre P, Bourret E, Joachim J. *In-vitro* comparative study of buccal mucoadhesive performance of different polymeric films. European journal of pharmaceutics and biopharmaceutics. 2001 Jul 1;52(1):45-55.

[24]. Shivane P, Solanki D. Formulation and evaluation of mucoadhesive buccal patch of timolol maleate. American Journal of PharmTech Research.2017; 7:335-48.

[25]. Muzib YI, Kumari KS. Mucoadhesive buccal films of glibenclamide: Development and evaluation. International journal of pharmaceutical investigation. 2011 Jan;1(1):42.

[26]. Nafee NA, Ismail FA, Boraie NA, Mortada LM. Mucoadhesive Delivery Systems. II. Formulation and *in-vitro/in-vivo* Evaluation of Buccal Mucoadhesive Tablets Containing Water-Soluble Drugs. Drug development and industrial pharmacy. 2004 Jan 1;30(9):995-1004.