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Corrigendum

FORMULATION, DEVELOPMENT AND *IN-VITRO* EVALUATION OF MUCOADHESIVE BILAYERED BUCCAL PATCHES OF MONTELUKAST SODIUM

[Int J Pharm Pharm Sci, Vol 4, Issue 2, p. 484-497]

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ABSTRACT

This is an corrigendum to the article "FORMULATION, DEVELOPMENT AND IN-VITRO EVALUATION OF MUCOADHESIVE BILAYERED BUCCAL PATCHES OF MONTELUKAST SODIUM" for Migraine Therapy' [Int J Pharm Pharm Sci, Vol 4, Issue 2, p. 484-497]. Author affiliation updated.

While reviewing our article, the principal author has realized the need of modification of header portion of front page (page no 484) as mentioned below:

Instead of "[1]School of Pharmacy, Singhania University, Pacheri Bari, Jhunkhunu-333515, Rajasthan, India,"

Above text "within inverted comma" to be modified as hereunder,

"[1]Research Scholar, School of Pharmacy, Singhania University, Pacheri Bari, Jhunkhunu-333515, Rajasthan, India,"

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Research Article

FORMULATION, DEVELOPMENT AND *IN-VITRO* EVALUATION OF MUCOADHESIVE BILAYERED BUCCAL PATCHES OF MONTELUKAST SODIUM

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ABSTRACT

The present study was an attempt to develop and evaluate mucoadhesive bilayered buccal patches to ensure satisfactory unidirectional release of montelukast sodium (MS). The patches were designed to release the drug for a prolonged period of time so as to reduce the frequency of administration of the available conventional dosage forms of MS. Experimental design was built to investigate the effect of two factors sodium carboxymethylcellulose (NaCMC) and Carbopol 974P (CP 974P), each at three levels, as independent variables on mucoadhesion strength and in-vitro residence time as dependent variables. The Design Expert software has given the optimized formulation as desired patches with mucoadhesion strength in the range 41–48 g and in-vitro residence time in the range 243–268 minutes could be obtained by using NaCMC amount in the range 2.1%w/v to 2.7% w/v and CP 974P amount in the range 0.6%w/v to 0.9% w/v. The patches were prepared by solvent casting method and also evaluated for key test parameter such as in vitro drug release. The impermeable backing layer prepared was of ethyl cellulose based to ensure unidirectional drug release. Efficiency of impermeable backing membrane found suitable for mucoadhesive dosage form was also evaluated. After 8 hours the drug lost from ethyl cellulose based backing membrane was <9% of the total amount. The drug release kinetics and mechanism was found to be function of suitable combination of polymers NaCMC and CP 974P. The drug release mechanism was found to follow non-fickian diffusion as release mechanism. Stability study was conducted at accelerated storage condition and prepared mucoadhesive bilayered buccal patches were found to be suitable with respect to morphological characteristics and with in-vitro drug release mechanism unaffected after three months.

Keywords: Montelukast sodium; Mucoadhesive buccal patch; Sodium carboxymethylcellulose, Carbopol 974P; Impermeable backing membrane.

INTRODUCTION

Asthma is one of the most common diseases affecting human for the period of 6–8 hours (hr) also during which most individuals are asleep. A limiting factor is the relatively short duration of bronchodilator activity of β2-adrenergic agonists. MS is a leukotriene receptor antagonist (LTRA) prescribed in maintenance treatment of asthma, chronic asthma attacks and to relieve symptoms of seasonal allergies [1].

Administration of montelukast through mouth dissolving tablet has been addressed in recently reported work [2]. But the known drawback of per oral delivery of montelukast is that it undergoes hepatic first pass metabolism. Thus it shows plasma or biological half-life of 2.5 to 5.5 hr, thereby limiting bioavailability up to nearly 64%. Also the repeated administration of MS through conventional mode of delivery leads to tolerance to its bronchodilator effect [3]. Hence, there is a need to develop controlled drug delivery system which can overcome the first pass effect, reduce the frequency of dosing and improve bioavailability. To control the delivery rate and as well as to increase the bioavailability, attempts have been made to deliver montelukast through buccal mucosa [4]. But not enough potential pharmaceutical work has been reported pertaining to mucoadhesive buccal bilayered patches of MS. The present work therefore describes such stable delivery system of MS, which will expectedly improve the biological half-life as well as bioavailability of montelukast.

The interest in novel route of drug administration occurs from their ability to enhance the bioavailability of the drugs impaired by narrow absorption windows in the gastrointestinal tract. Buccal drug delivery has lately become an important route of drug administration. Attempts have been made to formulate various mucoadhesive devices including tablets [5], films [6], patches [7,8] disks [9,10] strips [11] ointments [12] and gels [13]. Buccal patch may be preferred over adhesive tablet in terms of flexibility and comfort. In addition, they can circumvent the relatively short residence time of oral gels on the mucosa, which is easily washed away and removed by saliva.

A wide range of polymers of synthetic, semi synthetic and natural origin like carbopol, polycarbophil, sodium carboxymethylcellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose, eudragit RL-100, polyvinylpyrrolidone k30, chitosan and xanthan gum have been described for the formulation of bioadhesive systems, but none of these polymer possess all the characteristics of an ideal polymer (nontoxic, nonirritant, strong non covalent adhesion, sustained release, stable and cheap) for a bioadhesive drug delivery system. Carbopols, which are widely explored industrially for commercial applications, are excellent bioadhesives but with potential mucosal irritating character. Irritant properties of carbopols can be reduced by combining it with other non-irritant bioadhesive polymers like NaCMC, while still retaining relevant bioadhesiveness at targeted concentration range of polymeric combinations[14].

Therefore, the present study was aimed to design and characterize mucoadhesive buccal bilayered patches of MS prepared using a combination of NaCMC and CP 974P, backed with ethylcellulose based membrane which would improve the biological half-life as well as bioavailability of montelukast therefore expectedly also prolonging and improving the leukotriene receptor antagonism activity of MS.

MATERIALS AND METHODS

Montelukast sodium reference standard (Montelukast Purity: 99.93%) and Montelukast Sodium drug was kindly supplied by Ranbaxy Research Laboratories, Gurgaon and was used as received. Sodium carboxymethylcellulose, Ethyl cellulose (S.D. Fine Chemicals, Mumbai, India), Carbopol 974P (Loba Chemicals Private Limited, Mumbai, India), propylene glycol (Qualigens Fine Chemicals, Mumbai, India) were used. All other chemicals and reagents were of analytical grade.

Preformulation studies

Solubility studies

Solubility studies were performed according to the Higuchi and Connoras method [15]. A saturated solution of MS was prepared by shaking an excess amount in 2 ml phosphate buffer pH 6.8/distilled water at 25 ± 10°C room temperature for 24 h. The saturated solution was withdrawn, filtered and analyzed at 282 nm using UV visible spectrophotometer (Shimadzu 1601, Japan)