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Short Communication

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Comparison of Mucoadhesive Buccal Patches of Ondansetron HCl with Conventional Marketed Tablets

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Abstract

The purpose of this study was to design and evaluate sustained release mucoadhesive buccal patches of Ondansetron hydrochloride to bypass first pass metabolism thereby enhancing its bioavailability. The patches were fabricated using mucoadhesive polymers PVA, tamarind gum and chitosan along with a hydrophilic polymer PVP K30 by solvent casting method. A comparative in-vitro drug release study carried out with conventional marketed tablet showed that the prepared patches sustained the release upto 8hrs. The patches showed good flexibility and prolonged release upto 8hrs thereby achieving therapeutic efficacy and improved patient compliance. The sustained release patches are useful in reducing dose, dosing frequency and direct delivery of drug into the systemic circulation.

Keywords: Ondansetron HCl (ODN HCl), Poly Vinyl Alcohol (PVA), Tamarind gum, Chitosan, Marketed tablet.

Introduction

Oral drug delivery is the most preferable route of drug administration. However in case of the oral route there are several challenges such as first pass metabolism, instability in acidic environment, drug degradation in gastrointestinal environment and poor pharmacological response resulting into inadequate and erratic oral absorption. Hence to increase bioavailability, bypass first-pass hepatic metabolism and prolong the release thereby increasing therapeutic efficacy and improved patient compliance a more advanced dosage form should be formulated and one of the approaches is Buccal Drug Delivery System (BDDS). It also helps in achieving local as well as systemic effect. BDDS is a mucoadhesive drug delivery system where in the dosage form comes in intimate contact with the mucous membrane of the buccal cavity lining the inside of the cheeks.[1, 2]

Ondansetron HCl is a potent antiemetic drug which is a highly selective Serotonin 5HT3 antagonist. It is effective in the treatment of nausea and vomiting associated with cancer chemotherapy. It is well absorbed and undergoes first-pass metabolism, having oral bioavailability 60% and has a relatively short plasma elimination half life of 3 to 5 hours. The promising pharmacokinetics and physicochemical properties of ODN HCl

make it a suitable candidate for buccal drug delivery.[3]

Materials and Methods

Ondansetron HCl was received as a gift sample from FDC Ltd. (Mumbai, India). Tamarind gum was procured as a gift sample from Bhavna Gum Udhyog (Gujarat, India) and chitosan from CIFD (Cochin, India). PVP K-30, HPMC 15cps, Propylene glycol, DMSO, glacial acetic acid were obtained from SD Fine Chemicals Ltd. (Mumbai, India). PVA was supplied by CDH Ltd. (Mumbai, India).

Preparation of mucoadhesive buccal patches:

Ondansetron HCl buccal patches were prepared by solvent-casting method. The drug solution was added to the polymer solution and mixed thoroughly with the help of a magnetic stirrer. Propylene glycol and Dimethyl sulfoxide (DMSO) were then added as plasticizer and permeation enhancer respectively under stirring and this solution was poured into a glass Petri dish (9cm diameter) and allowed to dry at ambient temperature till a flexible film was formed. Dried films were carefully removed and cut into patches of 1.5cm in diameter, packed in aluminium foils and stored in airtight containers at room temperature for further study.[4] The various batches prepared are as given in Table1.

In-vitro drug release study:

Dissolution rate studies to assess the drug release from the buccal patches were carried out in USP apparatus II. 900 ml of phosphate buffer 6.8 was taken as dissolution medium and the release study was performed at 37 ± 0.50 at 50 rpm for 8 hours. Aliquots (5 ml) were withdrawn at specific time intervals for a period of upto 8 hours. Drug concentration in the withdrawn aliquots was assessed by UV spectrophotometer. Prepared formulations were compared with the marketed tablet.

Table 1: Composition of Buccal patches loaded with Ondansetron HCl

Name of Ingredients	F1	F2	F3
Ondansetron HCl (mg)	85	85	85
PVA (gm)	0.5	-	-
Tamarind gum (gm)	-	0.5	-
Chitosan (gm)	-	-	0.2
PVP K-30 (gm)	0.1	0.1	0.1
HPMC 15cps (gm)	-	-	0.2
Propylene glycol (ml)	0.5	0.5	0.5
DMSO (gm)	1	1	-
2% v/v Acetic acid (ml) q.s.	-	-	10
Water (ml) q.s.	10	10	-

Quantity of drug per 1.5cm diameter patch = 2.36mg

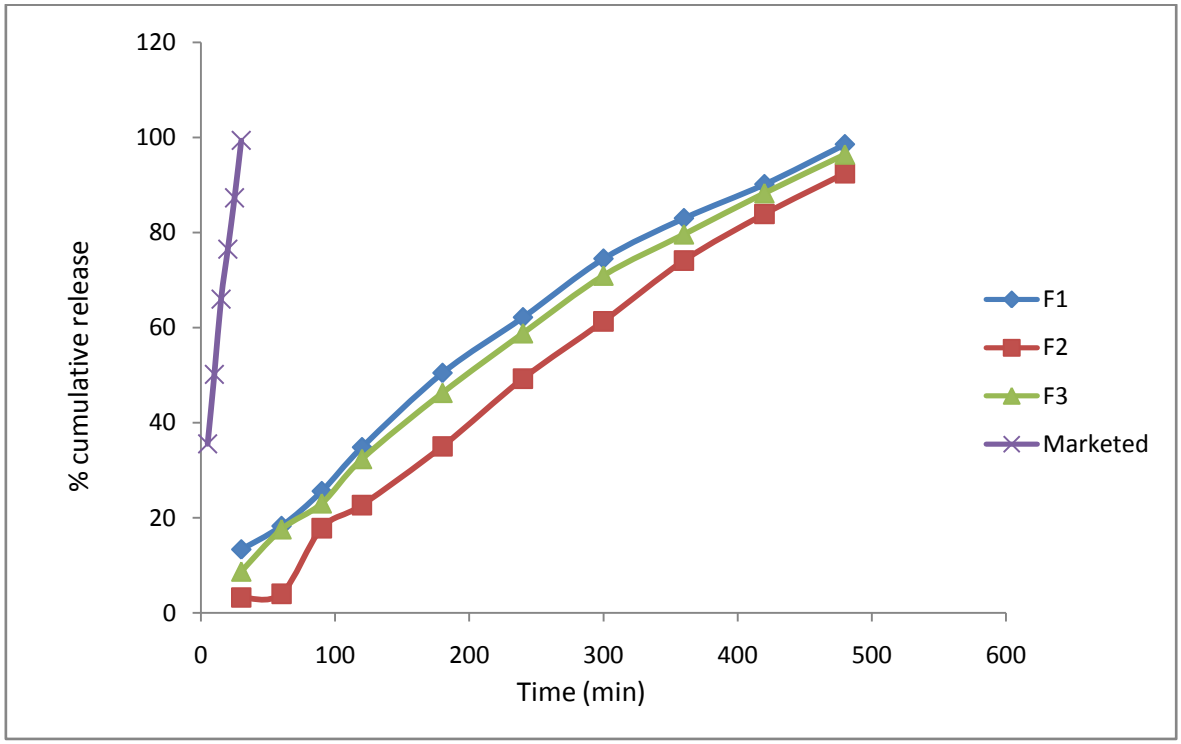

Figure 1: Comparison of In Vitro Release profiles of prepared formulations (F1-F3) with Marketed Tablet

Results and discussion

The Ondansetron HCl buccal patches were obtained as good flexible films with acceptable mucoadhesive strength, retention time, ex-vivo permeation and swelling properties. Drug content was found to be high (99.70%) and uniform in all formulations. Figure 1 depicts the desired dissolution pattern of the prepared formulations F1-F3 which showed a prolonged release of 8 hours in comparison to the marketed tablet which showed complete release within 30min of which F1 showed increased swelling, ex-vivo permeation and mucoadhesion strength.

Conclusion

This study clearly demonstrated that Ondansetron HCl can be successfully delivered via the buccal route. The buccal patches prepared by using mucoadhesive polymers PVA, tamarind gum and chitosan along with PVP K-30 can be a promising drug delivery system for achieving sustained and prolonged release, and thereby achieving better therapeutic efficacy and improved patient compliance compared to conventional marketed tablet. It is evident from the results that formulation F1 shows desired sustained release pattern and other evaluation parameters.

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