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Development and Evaluation of Mucoadhesive Buccal Patches for Rheumatoid Arthritis Treatment Using Lornoxicam Drug

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ABSTRACT

Mucoadhesive buccal drug delivery is one of the novel drug delivery system. Buccal drug delivery is safer mode of drug delivery system as buccal mucosa has an excellent accessibility, which lead to direct access to circulation through the internal jugular vein bypass the drug from hepatic first pass effect and avoidance of pre-systemic elimination within the GIT. Some of the NSAID already have been formulated and evaluated as muccoadhesive buccal patches but most of them still been unexplored. Buccal formulation of NSAID is promising formulation of near future. A few NSAID like ketorolac, aceclofenac, diclofenac etc.have been incorporated in buccal dosage form. In the present study, mucoadhesive buccal patches of lornoxicam were prepared using different polymers. The patches were prepared by using solvent casting method. Amongst all the prepared formulations, HPMCK4m and cabopol (1:1) showed better drug release of 76% ± 1.83 after 24 hrs. By reviewing the result obtained, on the basis of the invitro characterization it was cocluded that lornoxicam can be administered through buccal route as a matrix type buccal drug delivery system. Development of lornoxicam muccoadhesive buccal drug delivery patches using HPMCK4m and carbopol increases patient compliance.

Keywords: Muccoadhesive, lornoxicam, buccal, NSAID, polymer, novel.

Introducton:

Buccal drug delivery system is one of the novel drug delivery system. Buccal drug delivery also safer mode of drug delivery system and can be able to remove in case of toxicity and adverse effect. Buccal mucosa has an excellent accessibility, which leads to direct access to systematic circulation through the jugular vein bypasses the drug from hepatic first pass metabolism.mucoadhesion is the phenomenon between to material which are held together for prolong period of time by interfacial force. It isgeneraly referred as mucoadhesion when interaction occurs between polymer and epithelial surface. Buccal patches are highly flexible and much more deadly tolerated by patient than tablet. Some of the non-steroidal anti-inflammatory drug already have been formulated and evaluated as muccoadhesive buccal patches but most of them still been unexplored. Buccal formulation of NSAID like ketorolac, aceclofenac, diclofenac, etorocoxib, ketoprofen, piroxicam etc. Have been incorporated in buccal dosage form and been evaluated. In the present study of buccal mucoadhesive patches of lornoxicam were prepared using hydrophilic polymers and hydrophobic polymer by using solving casting method . Release study of lornoxicam patches indicate that the drug release form the formulate on varies with the different composition of polymer. Among all the prepared formulation containing hmpck4m and carpool show batter drug release after 24 hrs. By reviewing the results obtained, on the basis of the inviter matrix type buccal drug delivery system development in our lab. The type of polymer used to prepared buccal patches affects how well muccoadhesive preparation work. Buccal patches have been the advantages of easy exclusion. Low enzymatic activity, straight forward application and other capacity to include permeability enhancers, enzyme inhibitors or ph changer. Lornoxicam, a nonsteroidal ant inflammatory drug used in rheumatoid arthritis . it also indicate for the inflammation and swelling . Mucoadhesion has become an interesting topic for research over the last two decades, for its potential to optimize localized drug delivery, by intimate contact with the absorption site.

Oral Mucosa:

Total area of the oral cavity is 100cm. One third is the buccal surface which is lined with an epithelium of about 0.5 mm thickness. Oral cavity is that area of mouth delineated by the lips, cheeks, hard palate, soft palate and floor of mouth. Oral cavity proper which extends from teeth and gums back to the faucets (which lead to pharynx) with the roof comprising the hard and soft palate. The tongue project from the floor of the cavity.

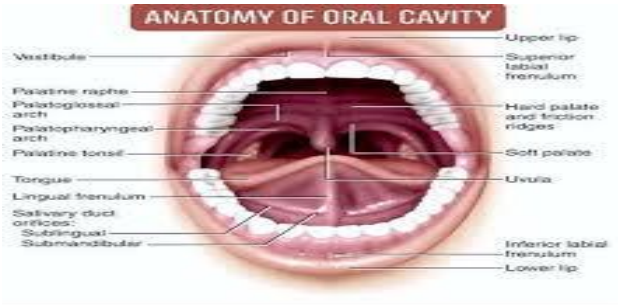

Fig.1

Material and Method:

Lornoxicam, Hpmck4m, Scmc, Crbopol1971p, Calcium Chloride, Propylene Glycol. Polyethylene Glycol 400, Distilled Water Were Required As A Gift From Ariston Pharmaceutical Put Ltd. Company Mandideep Bhopal All Other Chemical Are Of Analytical Grade.

Drug excipient compatibility studies:

The infrared IR spectra were recorded using an FTIR by the Ker pellet method and spectra were recorded in the wavelength region between 4000 and 400 cm-1. These spectra obtained for lornoxicam, polymer and physical mixture of lornoxicam with polymer were compared. Disappearance of lornoxicam peaks or shifting of peak in any another spectra was studied.

Solvent casting method

In this, all patch excipient including the drug co dispersed in an organic solvent and coated a sheet of release liner. After solvent evaporation, a thin layer of the protective backing material is laminate that is die- cut to form patches of the desired size and geometry.

Method mucoadhesive buccal patches will prepared by using solving casting method. Polymer vehicle we carried out by calculating the desire amount of polymer plasticizer and drug. The weight of polymer (hpmck4m, scum, carpool) incorporated in the film was 2% w/w. Each polymer has a different method of preparation. 50 ml normal water was taken in a beaker than hpmck4mdissolve than allow stirrer stand. Then 50 ml normal water was taken in a beaker dissolve carpool then stirred through glass road get viscous lump. Then 50 ml was taken in a beaker then scum dissolve continue stirred get lump and viscous. Then all polymer mixed in beaker and continue stirring get lump then calcium chloride 0.1% w/v then plasticizer 20% from the weight of polymer propylene glycol and drug 0.5% w/w were blended to the polymeric solution. The medicated gel was kept overnight at room temperature to obtained clear and bubble free gel. After that, this gel will be poured to the glass

petridishes be dried in hot air oven at 60-70 degree Celsius finally, the film wee cut into the required dimension, enveloped in aluminum foil.

Evaluation of Buccal Patches:

Thickness Uniformity:

The thickness of takes was measured by using electronic caliper with a least count of 4.3mm thickness was measure at three different points on the film and average reading.

Uniformity of Weight:

The patch of size 2*2 cm2 was cut and weight of each patches was taken individually the average weight of the patch was calculate by using electronic balance machine.

Folding Endurance:

The folding endurance was measured manually for the prepared patches. A strip of patch 2*2 cm2 was cut and repeatedly folded at the same place till it broken. The number of times the film could be folded at the same place without breaking gave the value of folding endurance.

Surface of Ph:

The determine of surface ph, three patches from each formulation were kept in contact with 1 ml of distilled water for 1 hr in a test tube . The ph was noted by bringing the electrode of ph meter near to the surface of the film and allowing it to equilibrate of one minute. The average reading and standard deviation of the patches were calculated.

Percentage of Moisture Uptake:

The patches were weighed accurately and placed in desiccators where a humidity condition of 80%-90% RH was maintained by using saturated solution of potassium chloride. The patches were kept until uniform weight is obtained, then taken out and weighed. The percentage of moisture uptake was calculated as the different between final and initial weight with respect to initial weight.

Percentage Swelling:

Individual patches from each formulation are weighed before and after being placed in petridishes containing 20 ml of simulated ph 6.8 phosphate buffer sol. For 1hours.

In vitro Drug Release Study:

As per the method mention by Rossi carlo et al (2004), calibration of lornoxicam in phosphate buffer ph 7.4 was done.

Stability:

The stability study was conducted for all formulation at 40 degree Celsius and 75%RH to investigate the effect if temp. On the drug content different film formulation. The

film was removed from the oven end of 0.7.14.21, 28 days and they were analyzed for drug content.

Results and Discusion:

As mentioned by parmar et al. (2020)' chandarsekar (2013)**,** propylene glycol has been recently reported to be a plasticizer, so it is selected as plasticizer in 20% w/w of polymer weight to impart flexibility and clarity to the patches. The incompatibility between the drug and excipient were studied by their spectroscopic IR spectral studies which indicate that there were no interaction between drugs and the polymers and copolymers used Moisture uptake of lornoxicam patches patches was increased in proportion of the concentration of polymer and also increases on the time of exposure and relative humidity respectively. Drug content uniformity test was carried out in order to make sure about the uniform dispersion of drug in the patch. The drug content was analyzed using UV spectrophotometer at wavelength 379nm. In comparision to placebo patch solution as a blank sample, the results of test patch solotions, indicates that the drug was uniformly dispersed. The procedure of prepared polymeric solution gives reproducible results. In vitro release studies of lornoxicam patches were carried out by using pH 7.4 phosphate buffer solution. The release data was observed. The formulations were uniform in their weight and, thickness with low SD value from 0.001 to 0.06, and almost uniform in their drug content. The film contained HPMC has highest folding endurance than the films contained HPMCk4m, SCMC and in combination with propylene glycol and polyethylene glycol. The HPMC contained buccal films showed highest bioadhesive. The film were late subjected to invitro drug release studies the release of the drug from film was dependent on the nature and proportion of the polymer. Invitro release studies were carried out using fabricated diffusion tube with cellophane membrane in phosphate buffer of pH 7.4 the prepared patches of plasticizer propylene glycol 20% concentration trial 1st are taken as best formulation after drying show in table no.2. pH of buccal film was determined to optimize both drug release and mucoadhesion. The surface ph of all formulations within plus minus 0.5 units of the natural pH. The value were found to be optimum to review good film properties show in table no.1 PEG 10% stick in Petridis and glycerin 20% stick in Petridis because glycerin are moisture absorb so trial 1 best formulation of patch. Glycerin is not proper formulation patches because glycerin it is moisture absorb. The preset work is the development and evaluation of mucoadhesion buccal patches using lornoxicam for the treatment of arthritis. It is developed with polymers like hpmck4m, scmc(semisythetic carboxy methyl cellulose), carbopol and evaluated for their stability studies. Preformulation study in this study buccal patches have prepared using varying percentage of carbopol 934p, HPMC and 50% w/w of propylene glycol plasticizer by solvent casting method**.**

The following preformulation study was performed for lornoxicam.

Melting point	222-227 °c
λmax	376 nm
pH	7.4
Solubility in methanol	42.98 µg/ml

Table No. 1

Evaluation of lornoxicam mucoadhive buccal patches

s.no.	INGREDIENT	solvent	quantity
1.	HPMCK4m		
2.	Sodiumcarboxymethyl celulose		
3.	Carbopol 1971p		
4.	PROPYLENE GLYCOL		
5.	polyethylene glycol		
6.	Calcium chloride		
7.	Distilled water		

Trial	Composition HPMCK4m:carbopol:SCMC	Thickness (mm)	Folding Endurance	Weight (mg)
Trial 1	PG 10%(propylene glycol)	4.31 ±0.04	>400	18±0.01
	PG 20%	4.86± 0.06	>400	20 ±0.02
	PG 30%	4.46± 0.008	>400	22±0.04
Trial 2	PEG 20%(polyethylene glycol)	4.47±0.002	>150	25±0.03
	PEG 30%	7.26±0.007	>150	26±0.04
	PEG 40%	8.05±0.004	>400	38±0.05
Trial 3	PEG 30%	5.67±0.003	>400	41±0.04
	PEG 40%	4.94±0.005	>400	38±0.05
Trial 4	Glycerin 10%	2.03±0.001	00	00
	Glycerin 20%	00	00	00
	Glycerin 30%	00	00	00

Table No. 2

Conclusion:

Lornoxicam, a non steroidal anti Inflammatory agent which selected for the preparation of buccal drug delivery system as it complies with physicochemical properties required to permeate through buccal mucosa. The mucoadhesive buccal film of Lornorxicam

were prepared by solvent casting method and were subject for evaluation parameter such as physical appearance, weight variation, thickness, folding endurance, drug content, moisture content, diffusion study. From the above studies, it is revealed that the present work was a satisfactory preliminary study of improving patient compliance of lornoxicam by development of buccal drug delivery system using ratio of HPMCK4m and carbopol and SCMC along with PG400 as plasticizer demonstrated modified release of the drug for 24 hrs. Further the therapeutic utility of this system to be established by pharmacokinetics and pharmacodynamic studies on human beings.

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