FORMULATION AND EVALUATION OF MUCOADHESIVE BUCCAL TABLETS OF OLMESARTAN MEDOXOMIL

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ABSTRACT:

Introduction: Among the various routes of drug delivery, the oral route is perhaps the most preferred. After oral administration many drugs are subjected to pre systemic clearance extensive in liver, which often leads to a lack of significant correlation between membrane permeability, absorption and bioavailability. Consequently,other absorptive mucosae are considered as potential sites for drug administration. Trans mucosal routes of drug delivery (i.e. the mucosal lining of the oral ,nasal, rectal, vaginal, ocular, cavities) offer distinct advantages over per oral administration for systemic effect. Buccal delivery is the drug administration through the mucosal membrane lining the cheeks (buccal mucosa). Among the various transmucosal routes, buccal mucosa has excellent accessibility, an expanse of smooth muscle and relatively immobile mucosa, hence suitable for administration of retentive dosage forms. Olmesartan Medoxomil has low oral bioavailability, due to extensive first metabolism hence selected for the formulation of buccal tablets.

Aim & objective: The aim of this study is to formulate and evaluate mucoadhesive buccal tablets of Olmesartan Medoxomil Inclusion complex's using various mucoadhesive polymers with an objective to enhance bioavailability and to evaluate the same using *in-vitro* and *ex-vivo* drug release studies.

Materials and Methods: Olmesartan Medoxomil, β-cyclodextrin,Sodium CMC,HPMCK4M, Sodium alginate, Magnesium sterate, Talc, Methanol, Potassium dihydrogen orthophosphate, Sodium hydroxide pellets, Mannitol respectively.

Methods: Olmesartan Medoxomil inclusion complexes were prepared by using carrier β-cyclodextrin in ratio of 1:1 by Kneading method. Nine formulations of buccal tablets were prepared using direct Compression method. The formulation design was optimized by solubility studies, ,Compatibility studies by Differential scanning Calorimetry, *in-vitro* evaluation(Weight variation, Thickness, Hardness ,Friability, Content Uniformity test, Surface pH, Swelling studies, Bioadhesive strength, Ex-vivo residence time, Ex-vivo permeation studies, Stability studies, *in-vitro* drug release studies.

Results and discussion: The results of *in-vitro* evaluation tests of the formulation were within Standard limits. Based on *in-vitro* drug release studies F9 formulation was found to be optimized with 92.92 % drug with zero order release and *ex vivo* permeation 69.66% of drug release within 8hrs.Acclerated stability studies for optimized formulation showed no change in colour, integrity, and no significant change in drug release.

Conclusion: The Mucoadhesive buccal tablet Olmesartan Medoxomil inclusion complex was successfully prepared and evaluated.The developed buccal tablet was one of the alternative route of administration to avoid first pass effect and to improve bioavailability through buccal mucosa.