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Mouth Dissolving Film of Antidiabetic Drug: Formulation & Optimization by 3^2 factorial design

P. Chandel[1], R. D. Bawankar[2]*, D. R. Mundhada[3]

[1]Student,Agnihotri College of Pharmacy, BapujiWadi, Ramnagar, Wardha – 442001, India
[2]AssistantProfessor,Agnihotri College of Pharmacy, BapujiWadi, Ramnagar, Wardha – 442001, India
[3]Principal, Agnihotri College of Pharmacy, BapujiWadi, Ramnagar, Wardha – 442001, India

Abstract : The objective of the present study was to formulate and evaluate Mouth Dissolving film of Voglibose. Voglibose with t1/2 4 hrs and absolute oral bioavailability about 60-65%,are Alpha-glucosidase inhibitors that act as competitive inhibitors of enzymes needed to digest carbohydrates: specifically alpha-glucosidase enzymes in the brush border of the small intestines. The films were prepared using solvent casting method using HPMCe-15, PVA as polymer and Polyethylene glycol 400 as plasticizer. HPMCe-15 was selected as polymer on the basis of their film forming property and inertness, while Aspartame is used as a sweetening agent, Pineapple flavor is used as a flavouring agent and to analyse the usefulness of DOE in the development and optimization of a Mouth Dissolving film of a model drug employing 3^2 full factorial statistical design. The drug-polymer compatibility study was carried out to determine the interactions, if any between the drug and the polymers used in the study. The FTIR and DSC study revealed that, polymers and excipients used were compatible with drug. Evaluation of mouth dissolving film for physical appearance, surface texture, thickness measurement, weight uniformity, drug content, folding endurance, surface pH, *In vitro* disintegration time, % Moisture Content, % Moisture uptake, % Moisture uptake as well as *Ex-vivo* permeation studies. Formulation MDF3 disintegrated in 27.46±0.5 seconds. The formulation MDF3 showed maximum % drug release of 94.68±1.02% in 10 minutes and concluded that MDF3 was superior and effective in achieving patient compliance. Optimized MDF3 batch when subjected to stability at 40± 2^0C temperature with relative humidity 75±5% for three months, indicating there was no degradation and change in film.

Keywords : Voglibose, Mouth dissolving Film, HPMCe15, PVA, PEG 400, FTIR, DSC, SEM, 3^2 Factorial Design.

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