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FORMULATION APPROACH FOR MUCOADHESIVE BIO-FLEXY STRIPS OF NANOSIZED BROMOCRIPTINE FOR ORO-TRANS LABIAL DRUG DELIVERY PLATFORM

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ABSTRACT

The aim of the current research was to formulate mucoadhesive flexy strips loaded with bromocriptine and evaluate its performance. Mucoadhesion can significantly improve systemic as well as targeted therapeutics. The oral bioavailability of bromocriptine is only 6%. Nanoparticulate form of bromocriptine was achieved by Novel method using 1,2,3-Propanetriol as nanosizant. Ten formulations (FAO1-FAO5 and FG1-FG5) having different ratios (1:1, 1:2, 1:3, 1:4 and 1:5) of biopolymer from *Anacardium occidentale* and Guargum were prepared by 'solvent casting method'. All the formulations were subjected to various evaluation parameters like appearance, thickness, surface pH, weight uniformity, content uniformity, folding endurance and *in-vitro* release study. All the strips were flexible, smooth and translucent in appearance. The thickness of all strips were in the range of 01mm to 02mm. Surface pH of all strips were in the range of 7.31 to 7.38. *In-vitro* release kinetics was performed using Franz Diffusion Cell apparatus and analyzed through BIT-SOFT 1.12. Formulation FAO4 was selected as the best formulation on the basis of different evaluation parameters and it followed Higuchi Matrix model with R^2 value 0.9463. The research work concluded that bio-flexy strips can be promising mucoadhesive dosage form for delivery of bromocriptine.

KEYWORDS: Bromocriptine, Nanosizing, Mucoadhesive, *Anacardium occidentale,* Biopolymer.

INTRODUCTION

Bromocriptine is an ergot derivative and has been available in market for more than 20 years. It has potent dopamine agonistic activity which stimulates post synaptic dopamine receptors. Bromocriptine stimulates hypothalamic dopaminergic receptors resulting in an increase in prolactin inhibitor factor, decreasing secretion of prolactin from the anterior pituitary thus used in treatment of hyperprolactinaemia. Bromocriptine also decreases growth hormone production. It is also used in acromegaly and Parkinson's disease.[1] In 2009 QR-bromocriptine (Cycloset™) was approved by FDA for the treatment of type 2 diabetes mellitus.[2]

Flexy strips have the ability to adhere mucosal surface and manufactured by Solvent casting method and Hot-melt extrusion techniques utilizing strip formers, plasticizers, and stabilizers. These mucoadhesive strips/ strips/ patches have several unique advantages ease of administration, flexibility, reduced dosing frequency, rapid onset of drug delivery, dose accuracy, easy storage and handling, improved bioavailability, dose reduction due to improved bioavailability thus reduces dose related side effects. Recently mucoadhesive buccal strips are incorporated in European Pharmacopoeia 7.4 which makes these dosage form widely accepted.[3]

The raw kernels of *Anacardium occidentale* belonging to family Anacardiaceae are rich in fat (48.3% of total weight), Proteins (21.3%) followed by carbohydrates (20.5%), Glutamic acid (4.60%) and tryptophan (0.32%). Vitamin E 0.58mg/100 g is the most abundant vitamin present in it. The reported potassium and sodium content are 6225mg/kg and 144mg/kg respectively. The total production of cashew kernels is led by India in the world.[4]

The inner side of labial mucosa is non-keratinized in nature and composed of stratified squamous epithelium.[5-6] It is supplied with mental nerve which is mandibular branch of the facial nerve (via the inferior alveolar nerve). Labial mucosa is highly vascularized and are supplied from the superior and inferior labial branches of facial artery, one of the six non-terminal branches of the external carotid artery. All muscles acting on the lips are supplied by the nerve of the second pharyngeal arch, the facial nerve (7th cranial nerve).[5-7]