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Formulation and Evaluation of Orodispersible Bilayer Tablet containing Fenoprofen Calcium

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ABSTRACT: Conventional compressed tablets are associated with certain limitations associated to their delayed plasma drug concentration and difficulty in swallowing (Dysphagia). Orodispersible tablets, seem to circumvent the above-mentioned limitation and can facilitate oral administration in pediatric and geriatric patients. Current work aimed to achieve rapid therapeutic effects; typically suggested for geriatric and pediatric patients because to enhanced compliance, bioavailability, simplicity of administration, and palatability. Fenoprofen Calcium orodispersible tablets were made using the direct compression method and a coprocessed superdisintegrant (Crospovidone + Ac-Di-Sol). The absorbance, MP, and FTIR spectra of the bulk drug were evaluated in order to characterise it. There was uniformity and repeatability in the measurements for tablet thickness, weight variation, percent drug, wetting time, in vitro disintegration time, and in vitro dissolution tests after compression. Within 25 minutes, all formulations (ODT1-ODT9) demonstrated a nearly 100% drug release rate. The fastest Fenoprofen Calcium release was recorded in the case of ODT9; in 10 min, 58.554%, and in 25 min, 98.72%. The current study concluded that increasing the amount of coprocessed superdisintegrants decreased tablet disintegration time and increased cumulative drug release, all of which resulted in increased absorption.

Keywords: Direct Compression, Fenoprofen Calcium, Coprocessed superdisintegrant, Factorial design.

INTRODUCTION

Orodispersible tablets (ODTs), according to the 10th edition of the European Pharmacopoeia, have a maximum disintegration time of 3 minutes and are a modern pharmaceutical formulation that patients readily accept (Deore *et al.*, 2021; Ingale *et al.*, 2021). Novel medicine administration methods, such as orodispersible tablets, are becoming more common (Essa *et al.*, 2022). It is advantageous because this pharmaceutical formulation does not necessitate the use of water during administration (Borse *et al.*, 2022). The term "arthritis" is frequently used to describe any condition that has an impact on the joints. The knees, wrists, fingers, toes, and hips are examples of joints, which are areas of the body where bones meet. These illnesses are marked by inflammation (which manifests as redness, heat, swelling, and sensations like pain) and the loss of function of one or more physical structures that link or support the body (Bullock *et al.*, 2019). Pain, swelling, and stiffness are common symptoms. Osteoarthritis (OA) is an abnormal remodeling of joint tissue within the affected joint including pathologic changes such as degradation of the articular cartilage, thickening of the subchondral bone, formation of osteophytes, variable degrees of inflammation of the synovium, degradation of ligaments and hypertrophy of the joint capsule (Gupta, 2017). Knees, hips, spines and joints in the hands are the commonly affected anatomic sites. Knee OA is the most common joint disorder in elderly individuals (Taoyu *et al.*, 2019). Fenoprofen Calcium is the calcium salt version of the fenoprofen, a propionic acid derivative. It have anti-inflammatory, analgesic, and anti-rheumatic activities by inhibiting both isozymes of cyclooxygenase, resulting in inhibition of prostaglandin synthesis by blocking the conversion of arachidonic acid to prostaglandins (Wanasakapant *et al.*, 1976). The half-life of plasma is approximately 3 hours. The two major urinary metabolites of ofenoprofen, glucuronide and 4'-hydroxyglucuronide, contribute for approximately 90% of the oral dose's clearance within 24 hours. 99% of fenoprofen is linked with albumin (Patterson *et al.*, 2002). Orally, 200 mg every 4 to 6 hours is the suggested dosage for the management of mild to moderate pain in arthritis. Fenoprofen Calcium are available in the market as conventional Tablets and Capsules (Rihana *et al.*, 2019).

MATERIAL AND METHODS

Materials

Fenoprofen Calcium was purchased from Yarrow Chem Products (Mumbai, India). Avicel, Ac-di-sol and