INTERNATIONAL RESEARCH JOURNAL OF PHARMACY

www.irjponline.com

ISSN 2230 – 8407

Research Article

FORMULATION, OPTIMIZATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF PIROXICAM USING HYDROTROPIC SOLUBILIZATION TECHNIQUE

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Article Received on: 24/11/17 Approved for publication: 27/12/17

DOI: 10.7897/2230-8407.0812255

ABSTRACT

Solubility is a most important parameter for the oral bioavailability of poorly soluble drugs. Dissolution of drug is the rate-determining step for oral absorption of the poorly water-soluble drugs, which can subsequently affect the in-vivo absorption of drugs. The delivery of such water-soluble drugs has been the subject of much research, as approximately 40% of new chemical entities are hydrophobic in nature and solubility of active pharmaceutical ingredients (API) has always been a concern for formulators. The objective of present work was to enhance the aqueous solubility of poorly soluble drug Piroxicam using hydrotropic solubilization technique and develop its mouth dissolving tablets which resulted in enhanced solubility and thus bioavailability of the drug. The present study included the formulation of mouth dissolving tablets of Piroxicam by incorporating suitable superdisintegrants, and subliming agent which were evaluated on the basis of pre and post compression parameters. Initially, physical mixtures and hydrotropic solid dispersions of Piroxicam, were prepared using selected hydrotrope i.e. sodium benzoate in different ratios. After evaluating the physical mixtures and hydrotropic solid dispersions, the particular HSD of the drug concerned, was screened out and selected for further formulation development in the form of mouth dissolving tablets. It was concluded that such novel formulation design could be extrapolated to many potential therapeutic candidates possessing poor aqueous solubilities targeting at overwhelming demand of enhanced bioavailability encompassing utmost economic relevance.

Keywords: Piroxicam; Solubility Enhancement; Hydrotropic Solubilization Technique; Hydrotropic Solid dispersion; Mouth dissolving tablets; Optimization

INTRODUCTION

The performance of orally administered dosage forms largely depends upon the inherent property of the drug candidate i.e. water solubility, which facilitates its absorption.[1] Recent researches have revealed the necessity of developing novel dosage forms together with ease of medication. ODTs are advantageous particularly for geriatric patients with whom conventional tablets and capsules are problematic in swallowing. Moreover, pediatric patients, due to immature development of muscular and nervous capabilities, also fail to ingest them. MDTs are the currently preferred dosage forms with higher patient compliance.

The oral tablets, when brought to dissolve in mouth, result in rapid absorption and quicker onsets. The drugs undergoing pregastric absorption elicit apparently increased oral bioavailability when presented as MDTs.[2]

Better dissolution and bioavailability rates, of poorly aqueous soluble drugs, can be attributed to the phenomenon of solid dispersion.[3] An increase in aqueous solubility of the chosen drug can be brought about by the addition of another solute which is attributed as hydrotropic solubilization (Fig.1). [4-5]

MDTs induce rapid disintegration (>1 min.) of the dosage form in the oral cavity and the transformed residue is easily swallowable. [6] Piroxicam is chemically, 4-hydroxy-2-methyl-N-(2-pyridyl)-2H-1,2-benzothiazine-3-carboxamide-1,1-dioxide. It is a selective COX-2 inhibitor used in the treatment of rheumatoid arthritis, osteoarthritis and other joint disorders. The poor aqueous solubility of the drug made difficulty in formulation of appropriate dosage form with better absorption characteristics.[7] Hence, the study included the formulation of MDTs of Piroxicam using hydrotropic solubilization method.

MATERIALS AND METHODS

Drug sample and carriers, used in the study were obtained from various companies of repute. Piroxicam -Ramdev Chemicals, Thane, Ascorbic acid, Sodium benzoate, Sodium acetate, Camphor, MCC & Magnesium Stearate-CDH Pvt. Ltd. Mumbai, Crospovidone & CCS-Vardha Biotech, Mumbai, Talc-Rankem and Mucin-Vivan Life Sciences, Mumbai etc.

SELECTION OF HYDROTROPE FOR POORLY AQUEOUS SOLUBLE DRUG

Equilibrium solubility determination at room temperature

The different dissolution media, consisting of distilled water, 20% solution of sodium acetate, sodium benzoate and ascorbic acid, were added with excess amounts of the drug separately and shaken (12 h at 28°±1°C) mechanically, equilibrated (24 hrs) and centrifuged (5 min at 2000 rpm). The supernatant obtained in each case, was passed through whatman filter paper (No. 41). Each filtrate was suitably diluted and analyzed spectrophotometrically.[8]