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FORMULATION AND IN VITRO EVALUATION OF IMMEDIATE RELEASE SOFTGEL OF NAPROXEN SODIUM

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ABSTRACT: Oral drug delivery has been known for decades as the most widely utilized route of administered among all the routes that have been employed for the systemic delivery of drug via various pharmaceutical products of different dosage forms. The reasons that the oral route achieved such popularity may be in part attributed to its ease of administration and the belief that oral administration of the drug is well absorbed. One such area of research is design of Softgel technology. Softgel technology is one of the most attractive and promising approach for increasing oral bioavailability by means of increasing solubility of the poorly soluble drug. Naproxen Sodium is one of the most important Non-steroidal anti-inflammatory agents used in the treatment of acute to chronic pains, inflammation and it belongs to BCS class-II drug so as to increase its aqueous solubility for enhancing the bioavailability, it is formulated as a liquid filled soft gelatin capsules.

Keywords : Softgel, Naproxen Sodium, bioavailability, capsules

INTRODUCTION

Soft gelatin capsules or softgels are a single-unit solid dosage form, consisting of a liquid or semi-solid fill enveloped by a one-piece sealed elastic outer shell. The amount of drug or extract together with adjuvant is enclosed within a globular, oval or other shape of a soft shell. Soft gelatin capsules offer the possibility of delivering a liquid in a solid oral dosage form. The softgel can contain the active ingredient in solution, suspension or emulsion which will inherently lead to better absorption of the active ingredient as compared with delivery in a tablet or as a powder. Liquid filled softgel have beneficial to oxidative or hydrolytic degradable drugs. The liquid is prepared and encapsulated under a protective nitrogen atmosphere and the subsequently dried shell has very low oxygen permeability. The shell may be transparent and opaque. Opacity provides protection for photosensitive substances. Softgel capsules are also protected against UV radiation and light, which provides stability to the supplement and minimizes the formation of free radicals, and prevents especially rancidity.Soft gelatin capsules offer many advantages in comparison with other delivery systems. They are easy to swallow, have no taste (unless gelatin is intentionally flavored) odors and provides an elegant look.

RESEARCH METHODOLOGY

Gift sample of Naproxen sodium is received from M/s Merck Pharma ltd. Mumbai and the soft gelatin capsule shells are also received from the same factory .The remaining ingredients like propylene glycol, povidone, lactic acid etc are used from RIPS laboratory raw materials. Pre-formulation testing is an investigation of physical and chemical properties of a drug substance alone and combined with excipients. It is the first step in the rationale development of the dosage forms. Pre-formulation studies yield necessary knowledge to develop suitable formulations. It gives information about the nature of the drug substance. Hence, the following pre-formulation studies were performed for the obtained sample of drug.

RESULTS & DISCUSSIONS

The basic goal of formulation is to achieve an enhanced bioavailability that is therapeutically effective and non-toxic, when compared to other oral solid dosage forms. The design of proper dosage form is an important element to accomplish this goal. One such area of research is design of Softgel technology. Softgel technology is one of the most attractive and promising approach for increasing oral bioavailability by means of increasing solubility of the poorly soluble drug. Naproxen Sodium is one of the most important Non-steroidal anti-inflammatory agents used in the treatment of acute to chronic pains, inflammation and it belongs to BCS class-II drug so as to increase its aqueous solubility for enhancing the bioavailability, it is formulated as a liquid filled soft gelatin capsules.. Preformulation study was performed by formulating binary mixtures of drug with selected excipients. Binary mixtures were screened for physical appearance at initial and 40°C 2°C / 75% ± 5% RH, 4 weeks in close condition. Physical observations of binary mixtures and FTIR study revealed that there is no incompatibility between Naproxen Sodium and selected excipients in the formulation, when exposed to accelerated stability condition of 40˚C/75%RH for 1 month. UV spectrophotometric analytical method was developed for the model drug in pH 7.4 Phosphate buffer. Absorption maxima were found to be at 272 nm and the linearity was fixed between the ranges of 10 to 50 µg/ml. Various physical properties of like hardness, surface characteristics, practical size, pH weight variation and rupture time can significantly affect the rate of dissolution of drugs contained in a formulation. Various formulation trials of Naproxen Sodium Soft gelatin capsules were developed using various excipients for aqueous based fill formulation and gelatin shell formulation. Results of evaluation parameters like hardness, weight variation, pH of fill medicament, assay, disintegration test and encapsulation parameters were evaluated. Observations of all formulations for physical

characterization had shown that, all of them comply with the specifications of official pharmacopoeias and/or standard references. The formulations was optimized for binder, re-crystallization inhibitor, solubilizer, pH modifier for fill formulation and plasticizer, different bloom strength of gelatine for gelatine shell formulation and evaluating different trials (F1-F8). Formulation F8 had showed better release profile.

CONCLUSIONS

The in vitro drug release data obtained were extrapolated by zero order, First order to know the mechanism of drug release from the formulations. The release kinetics shows that the release of drug followed first order release in all the formulations. As the drug release was best fitted in First order kinetics, indicating that the rate of drug release is dependent on concentration. From the said observations it can be concluded that combination of lactic acid, povidone, propylene glycol, water, PEG 400, glycerin, sorbitol special and gelatin has shown effective release of Naproxen Sodium by increasing solubility and enhancing bioavailability. Hence it can be evident that by formulating the Naproxen Sodium soft gelatin capsules by softgel technology which results in more effective release of drug, increased solubility and oral bioavailability may also be enhanced.

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