Israa H. Al - Ani et al /J. Pharm. Sci. & Res. Vol. 8(1), 2016, 29-34

ISSN:0975-1459
Journal of Pharmaceutical Sciences and Research
www.jpsr.pharmainfo.in

Preparation of Ibuprofen as Pediatric Candies

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Abstract

Purpose: to present model drug (Ibuprofen) as gelatine candies for paediatric use.

Methods: Bovine gelatine was used as the vehicle for the model drug ibuprofen. Compatibility of ibuprofen and gelatine was studied by UV and IR spectrophotometry and by kinetic study. The gelatine candies were prepared by dispersion of all ingredients in phosphate buffer pH 7.2 after optimization of concentration of gelatine and other additives, then poured in Teflon moulds, left to solidify at room temperature.

Candies were evaluated for drug content uniformity, drug release and efficiency of the preservative used (methyl paraben). Preliminary stability study at 40°C and 75% relative humidity (RH) was also done for three months .

Ten kids age (4-7) years participated in the evaluation of taste, consistency and handling ability using "faces scale" and according to the regulations of Jordanian FDA.

Results: this study showed good compatibility of IB with gelatine, fast and almost complete release of and high efficiency of preservative used.

The prepared candies were found stable at 40°C, 75%RH for three months. Results also showed high rate of acceptance of this medicated candies by kids.

Conclusion: Edible gelatine candies can be used to deliver ibuprofen to kids successfully.

Key words: *gelatine, ibuprofen, paediatric formulation.*

Abbreviation : IB (ibuprofen), GL (gelatine), FDA(food and drug administration), RH (relative humidity)

1. INTRODUCTION

Safe and effective pharmacotherapy for paediatric patients requires the timely development of medicines and information on their proper use appropriate to the age, physiological condition and body size of the child. Formulations developed specifically for children are often needed.[1]

Paediatric practice requires a range of dosage forms that are acceptable at different ages and abilities and a range of strengths or concentrations allowing administration of the correct age-related dose. Seriously ill children will require intravenous drug administration and will prefer this to frequent intramuscular injections. For less serious illness and long-term administration the oral route will be preferred but other routes such as buccal, nasal, transdermal and rectal can be useful in some circumstances.[2]

Developing paediatric formulations is a very challenging subject, there are a lot of parameters that should be taken into account and there are still many open questions. Solid dosage form present some issues, as children have difficulty swallowing whole solid drug carrier like tablet or capsule. Moreover providing age-appropriate doses at different strengths is a big issue , while problems in dosing accuracy, stability, palatability and unknown bioavailability of compounded products exist in liquid forms.[3] However, The vast majority of paediatric formulation are for oral administration. McNally and Railkar state that 90% of paediatric formulation are for oral adminstarion.[4]

Gelatine is a mixture of protein and polypeptides products derived by hydrolysis of animal collagen, contained in bones and skins.[5] All reputable gelatin manufacturers today follow the Quality Management System according to ISO 9001. [6] For pharmaceutical grade gelatins, strict regulations from the Food and Drug Administration (FDA), the European regulation and European Pharmacopoeia must be met.[7] The safety of gelatine has been studied by many workers as an edible substances, no reported data about restriction of its use especially for kids are available. [8]

Ibuprofen is non steroidal antiinflamatory agent which is widely used for paediatrics as analgesic antipyretic and antiinflamatory in management of fever, pain and rheumatoid arthritis.[9] In this work an attempt to use gelatine edible candies as dosage form for paediatric use using ibuprofen as model drug.

2. MATERIALS AND METHODS

2.1 Materials

Bovine Gelatin was kindly given as gift from Zhuhai Ting Kai (China) Ibuprofen and methylparaben were given as gifts from Dar Al-Dawa in Amman(Jordan) , glycerol, different colorants, flavours (of Rimon Chemicals Est, Germany), sucrose were all given as gifts by HIKMA pharmaceuticals in Amman(Jordan).

2.2 Methods

2.2.1 Spectrophotometric analysis of Ibuprofen (IB) and Gelatine (GL)

A sample of IB in phosphate buffer pH 7.2 was scanned using Ultaviolet-visible spectrophotometer : Jasco V530, Japan. The spectrum was in agreement with references.[10] A wavelength 262 nm was chosen to construct the calibration curve. This buffer was chosen because it will be used in preparation and dissolution study.

A stock solution of 0.1 % of IB in phosphate buffer pH 7.2 was prepared by dissolving the powder drug in pre-prepared buffer, sonication then filtration. Series of dilutions were prepared and U.V absorbance at 262 nm was