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Preparation and evaluation of a new gel formulation of acetominophene

Dr.Hassen A.H.Bennasir*

**Department of Pharmacology & Toxicology*, Faculty of Pharmacy, Omar Al-Mukthar University, Derna, Libya.

***Corresponding Author: Dr.Hassen A.H.Bennasir**

ABSTRACT

The occurrence of oral semisolid dosage form in pharmaceutical field is rare. Oral gels are preparations designed to produce a greater patient compliance especially in pediatrics due to its palatability and elegant in appearance. Acetaminophen, a Para aminophenol derivative is a potent analgesic and antipyretic with weak anti-inflammatory activity.The aim of this study is based on the preparation of the gel form of the acetominophene and evaluate the screening effects of the newly formulated gel by using the animal model.

Objective

The present study is focused to formulate the acetominophene gel and study its properties and evaluate its screening effect on rabbits. The formulated gel was studied for its Drug content and its stability at room temperature for stipulated number of days.

Methods

The various excipients used for the formulation of the gel was added to proportion and batch sizes of100 ml was prepared .The gel considered for this formulation was carbomer. The carbomer is hydrophilic and produces sparkling clear gel when? neutralised with alkali. Carbomer disperses in water to form acidic colloidal solutions of low viscosity which when neutralised with alkali to produce high viscosity gels. So, carbomer was considered for our formulation.

Results

The properties of the newly formulated drug had the properties of the gel and the drug content and the stability of the drug showed significant results .The screening studies on the animal model yielded desired results

Conclusion

The study confirmed the properties of the acetominophene in the newly formulated gel and its effect for its anti pyretic activity is also achieved for the gel formulated drug.

Keywords: Acetominophene, Carbomer, propylene glycol, Aspartame, Sunset yellow FCF, Screening, Antipyretic activity.

INTRODUCTION

Formulation of any pharmacologically active drug is the crucial step that determines its use. The success of any medicinally active ingredients lies on the proper design of the drug and formulating an usable and therapeutically effective form.

Oral dosage form

It is the most convenient dosage form and it is widely used. The cost of formulation is also low on comparing the other dosage forms. Patient compliance is also good.

MATERIALS AND METHOD

The following **Drug and chemicals** are obtained from Egypt and are matched with pharmacopeia standards. Acetominophene was obtained in the form of tablet of 250mg and it was directly used the preparation. Carbopol 934 U.S.P which is used for its gelling property was obtained in powdered form and was dispersed in water to form acidic colloidal solutions of low viscosity and was neutralised with alkali to produce high viscosity gels. The viscosity adjusting agents used are Sodium hydroxide (0.1 N) and Hydrochloric acid. Propylene glycol was the solvent used which is a clear, colourless, viscous, odourless liquid having a sweet taste resembling that of Glycerol and it is easily miscible with water, Acetone, Glycerine and chloroform .Sunset Yellow FCF was used as a colouring agent which is easily miscible in water. Aspartame was used as a sweetener and strawberry as a flavoring agent.

Animals

To demonstrate the antipyretic property of the formulated acetominophene gel male and female rabbits aged 3 to 4 weeks Malta breed animals were used. Animals were kept in animal house at an ambient temperature of 25 - 30°C and 45 - 55% relative humidity with a 12 h each of dark and light cycle. Animals were fed with fresh greens and vegetables and water *ad libitum.*

Preparation of acetominophene gel

Acetominophene (250 mg) was dissolved in 5 ml of propylene glycol and mixed with 80ml of purified water with constant stirring. Carbomer 2g was dissolved in l0ml of purified water seperately and made acidic with a few drops of hydrochloric acid (0.lN). The carbomer solution was then added to the drug solution followed by amaranth, Sunset yellow FCF and strawberry and mixed well. The solution was then adjusted to the required weight and finally neutralised with a few drops of sodium hydroxide to obtain the gel. The pH of the gel was determined using universal pH paper. The preparation was then used for further studies. The formulation quantities used were shown in Table I .

Methodology

The screening of the formulation of the acetominophene gel was performed on the basis of the screening of the drugs for its anti – pyretic activity.

Experimental procedure

Pyrexia or fever is the common manifestation of many diseases and the common cause for fever is infection. The animals were divided into control and experimental animal's .Pyrexia was induced to the experimental animals by injecting milk of volume 4ml /100g subcutaneously. Control animals were just fed with the regular diet during this period. The test drug which is the formulated gel was given to the experimental animals 1 hour before the milk was injected .The formulated gel was given orally to the experimental animals of volume 5ml / animal .The experiment was studied for the inhibition of the increase of temperature for the experimental animals . Body temperature of all the animals were recorded, for its initial body temperature. The experimental animals temperature was recorded at an hourly interval for 4 hours after the milk was injected .The temperature was recorded for 45 seconds, using a lubricated thermister probe inserted 3cms into the rectum. The results obtained from the screening studies are tabulated in Table –II.

RESULTS AND DISCUSSION

The formulation was evaluated for the following
a. Drug content
b. Stability

Estimation of drug content in the formulation

The drug content in the formulation was determined as per the procedure described in Indian Pharmacopoeia 1996. 5g of the gel equivalent to l25mg acetominophene was weighed and dissolved in 0.lN sodium hydroxide solution. The solution

was then diluted to 500ml in a standard flask using 0.lN sodium hydroxide as the solvent. To 5ml of the resulting solution added more 0.lN sodium hydroxide solution and adjusted to 100ml in a standard flask. The absorbance of the final solution obtained was observed at 243nm by spectroscopic method. The drug content was calculated from the formula E1cm1% = 715.

Stability studies

Stability study was performed on the formulation in order to ascertain the interaction between the drug and the excipients on exposure to ambient temperature conditions over storage. The sample was stored at 25°C and withdrawn at 5th 10th, and 15th day for analysis of the drug content and also pH of the formulation.

Drug content in the formulation

The drug content in the acetominophene gel formulation was found to be 96 .4 %.

Stability studies

The results of the stability studies showed in Table III, that the formulation did not show any significant change in the percent drug content while the pH of the sample stored at 25°C showed a very slight decrease.

Table.1.

Ingredient	Quantity
Acetominophene	250 mg
Carbopol	2g (2%)
Sodium hydroxide	Q.S
Hydrochloric acid	Q.S
Propylene glycol	5ml
Sunset yellow FCF	0.01g
Aspartame	0.10g
Strawberry	0.01g
Purified water	100ml
Batchsize	100g

Screening studies

Table - II

Control Animals	**Animal I**	**Animal II**	**Animal III**	**Animal IV**
Initial temp	34.8	35	34.9	**34.5**
Temp after120 mins	34.8	34.9	34.9	**34.2**
Temp after 180 mins	34.8	34.9	34.9	**34.1**
Temp after 24 hours	34.9	34.9	34.6	**34.2**
Exp. animals	**Animal I**	**Animal II**	**Animal III**	**Animal IV**
Initial temp	35	34.8	35.2	35.2
Temp after 120 mins	35	34.9	35.8	35.3
Temp after 180 mins	35.3	34.9	36.6	35.4
Temp after 24 hours	35.4	35.0	38.9	35.4

N.B: All the Temperatures listed in the table are in º C

Table III

Sample	Temperature **25C°**			
Formulation Drug content (%)	0 day	5 days	10 days	15 days
	96.4%	96%	95.72 %	95.04%
PH	6.8	6.8	6.7	6.7

DISCUSSION

In this study, the oral gel formulation of acetominophene was developed with carbopol 934. The formulative ingredient was carefully selected in consistent with the requirements of a palatable preparation. Considerable importance has been given to the organoleptic properties of the formulation that can influence the psychology of the children. Sunset yellow FCF as a coloring agent ,aspartame as a sweetening agent and strawberry as flavoring agent were used in the formulation with a view to fulfill the desirable organoleptic characteristic. The PH of the formulation was also taken care because too acidic or too basic formulation might not be acceptable and hence the chosen PH of the formulation were also stabilized .From the Screening studies obtained from the gel formulation results it was evident that the function of the formulation was effective on the experimental animals as the drug had influence on the pyrexia.

The gel formulation can provide better absorption characteristics and hence the bioavailability of drug. A thorough investigation into the stability characteristics of the gel formulation over an extended period of time may provide scope for its therapeutic use for adults and more so for children.

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