



FORMULATION AND EVALUATION OF MEDICATED GUMMIES CONTAINING PARACETAMOL AND AGAR-AGAR

¹Laxmi Gupta, ²Sarvesh Patil, ³Rida Kable, ⁴Dnyaneshwar Sharma, ⁵Mrs. Shivani Pawar

¹Student, ²Student, ³Student, ⁴Student, ⁵Guide

Department of Pharmacy

Chattrapati Shivaji Maharaj University, Panvel, Navi Mumbai, Maharashtra, India

ABSTRACT :-

Viral fever and body ache may be common in children to resolve this paracetamol tablets, capsules and syrups are in frequent use which may be bitter in taste and minors may refuse it's intake. To resolve this problem and improve patient compliance we have formulated and evaluated a paracetamol gummy, which gives analgesic and antipyretic effect, mixed in with agar, a natural gelling agent derives from seaweed (red algae). The idea behind these gummies is to make taking medications more enjoyable, especially for children who might not like swallowing pills or taking oral suspensions.

Key-words:- Paracetamol, Agar, Gummies, Children

INTRODUCTION :-

Due to the low cost of treatment, simplicity of administration, patient compliance, and adaptability in formulation, the oral route of medication administration is the most popular. The conventional dosage forms like tablets, capsules, syrups etc are inconvenient for paediatric patients because of difficult to swallow tablets and capsules or unpleasant taste of drug. As a result, the demand for developing new technologies has been increasing day by day. Medicated gummies is designed to improve patient compliance, acceptability and increase oral retention time. They are generally considered more convenient than syrups or tablets, especially for paediatrics. Gummies are easy to chew and swallow, where as syrups may require measuring and pouring which, can be messy and time consuming. Paracetamol is commonly used as analgesic and antipyretic, whereas agar is a natural substance which is derives from seaweed that has gelling properties. Medicated gummies are safe and effective. It is a popular option for those who have difficulty swallowing pills or dislike the taste of syrups.



Fig. 1: Medicated Gummies

MATERIALS AND METHODS:-

MATERIALS:-

1. Paracetamol:-

Physical state:- Solid

Colour:- White

Odour:- odourless

Solubility:- It is soluble in water, acetone, and organic solvents, soluble in seventy part of water and 7 parts of ethanol, slightly soluble in chloroform and ether.

Melting point:- 168 °C-172 °C

Boiling point:- 420 °C

Description:- It is an NSAID drug and most frequently used. It is sold as OTC analgesic. It is used to treat headache, mild migraine etc..

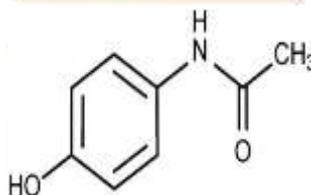


Fig. 2: Structure of Paracetamol



Fig. 3: Paracetamol

2. Sucrose :-

Physical State :- Crystalline or powdery solid

Colour:- white

Odour :- Odourless

Solubility:- It is soluble about 12% in 95% ethanol at room temperature

Melting point:- 186°C

Description:- sucrose is a molecule comprised of two monosaccharides- glucose and fructose. Chemically it is C₁₂H₂₂O₁₁.

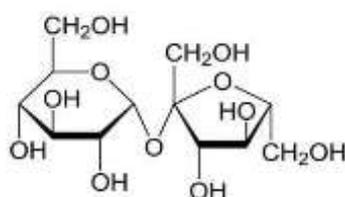


Fig. 4: Structure of Sucrose



Fig. 5: Sucrose

3. Agar- Agar:-

Physical state:- solid

Colour:- yellowish

Odour:- odourless

Setting point:- 32°C to 45°C

Melting point:- 85°C to 95°C

pH:- 6.5 to 7.5

Solubility:- boiling water



Fig. 6: Agar-agar

4. Sorbitol :-

Physical state:- crystalline powder

Colour:- white

pH:- 6-7

Description:- It is found naturally in fruits and vegetable. It helps protect against tooth decay.

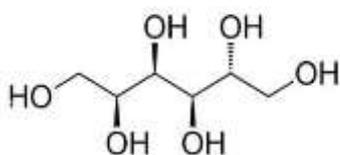


Fig. 7: Structure of Sorbitol



Fig. 8: Sorbitol

5. Sodium benzoate :-

Physical state:- crystalline powder

Colour:- white or colourless

Odour:- odourless

Melting point:- 410°C

Description:- It is used as preservative in various products.

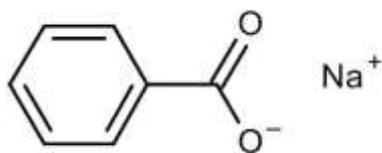


Fig. 9:- Structure of Sodium Benzoate



Fig. 10:- Sodium Benzoate

1. Strawberry flavour :-

Physical State:- liquid

Colour:- colourless

Odour :- Sweet

Solubility:- Soluble

Description:- It is used as a flavouring agent . It is fruity, caramel and sweet.



Fig. 11:- Strawberry Flavour

6. Beetroot extract :-

Physical state:- liquid

Colour:- pinkish red

Description:- It is a natural colouring agent. It also contain a significant amount of vitamin A and C, calcium, iron, potassium, protein and carbohydrates.



Fig. 12:- Beetroot extract

METHOD OF PREPARATION OF GUMMY :-

1. The method of gummy preparation includes preparation of two solutions, i.e., a solution of water and sugar and a solution of agar and water.
2. In a beaker add 8 g sucrose and 4.5g to 8ml of water in a beaker. This solution was heated on medium high while being stirred with a glass stirrer.
3. Adjust the temp. to a point where the temp. of the solution doesn't rise above 130°C.
4. Keep heating until viscous sugar syrup is formed. Avoid overheating to prevent the caramelization of sugars.
5. Once a thick, consistent syrup is obtained, turn off the flame. Lower its temp. to 60°C.

6. In another beaker 1.8 gm of Agar was mixed with 3ml of water and heated for a few min. on low heat.
7. Then pour the Agar into the warm sugar solution & mix thoroughly, & then heat the mixture for a few seconds to 70°C
8. Add 1.25gm of Paracetamol to the above mixture and stir to form a uniform solution. Now add 2.52ml of flavourant, add 1ml of colorant & 0.025gm of Na benzoate, 1/1, to the solution & mix it thoroughly.
9. Lubricant the silicon mould with glycerine to avoid sticking. Pour the warm mixture into the mould & tap them on the shelf to even up the level of fillings.
10. Remove & wipe any excess solution from the mould.
11. Place the mould in a safe place at room temp. for 60 mins.



Fig. 13:- Ingredients



Fig. 14:- Weighed chemicals



Fig. 15:- Preparation



Fig. 16:- Gummies in mould



Fig. 17:- Gummy Formulation 1



Fig. 18:- Gummy Formulation 2



Fig. 19:- Gummy Formulation 3

FORMULATION TABLE:-

Ingredients	F1	F2	F3
Sucrose	7g	8g	8g
Sorbital	4.5g	3g	5g
Agar-Agar	1.580g	1.730g	1.902g
Colorant	1ml	1ml	1ml
Paracetamol	1.25g	1.25g	1.25g
Flavorant	q.s.	q.s	q.s.
Na Benzoate	0.025gm	0.025gm	0.025gm

Table 1:- Formulation table for gummies

Formulation 3 was found to be optimized batch and it was further tested for evaluation.

EVALUATION PARAMETERS:-

1. Physical Appearance:-

All the prepared gummies are visually observed for their colour, shape, odour, taste and texture.



Fig. 20:- Medicated gummies

2. Thickness:-

The thickness of a gummy were measured using Vernier Calliper. The thickness of 5 gummies were checked.



Fig. 21 Vernier calliper

3. Weight Variation:-

A total of 10 gummies were weighed, with the average weight being determined after the total weight was added up.

Weight variation = individual weight – average weight/ average weight×100



Fig. 22:- Weighing balance

4. pH:- The pH of gummies was checked by using digital pH meter.



Fig. 23:- Digital pH meter

5. Dessicator :-

One gummy was weighed and then crushed in a mortar and pestle. From there 1g of the sample was weighed and dried for 24hrs in dessicator. The sample is weighed after 24hrs.

$$\% \text{ moisture} = \frac{\text{initial wet weight} - \text{dry weight}}{\text{dry weight}} \times 100$$



Fig. 24:- Dessicator

6. Titration :-

Table 2 :- Titration readings of gummies

Sr. No.	Initial Reading	Final Reading
1.	0	48.3
2.	0	47
3.	0	45.6



Fig. 26:- Titration of F1, F2 and F3 formulation

RESULT :-**Physical appearance :-**

Table 3 :- Physical appearance of gummies

Property	Inference
Colour	Pinkish red
Shape	Heart
Odour	Fruity
Taste	Sweet
Texture	Soft

Other evaluation parameters:-

Table 4:- Other evaluation parameter

Parameters	Results
Thickness	1.8cm
Weight variation	0.02%
pH	6.10
Drug content	93.92%
Moisture content	1%

DISCUSSION:-

One of the key elements of medicine administration is patient compliance. In the current study, sweetened gummies containing paracetamol and agar were developed for the successful management of analgesic and antipyretic in paediatric. As we know that paracetamol is very bitter in taste, due to which provoked and made realize the necessity to develop a novel drug delivery form for those paediatrics in order to increase compliance among them and increase the palatability. So, after immense effort, this research finally resulted in the formulation of the flavouring for paracetamol gummies for paediatrics. Evaluation parameters were performed, including organoleptic evaluation, weight variation, pH and drug content evaluation UV spectrophotometer.

Formulation 1: It doesn't set properly.

Formulation 2: Gummies becomes sticky within certain period of time, and it doesn't remain stable for longer period.

Formulation 3: Gummies were soft and stable and it was tested for further evaluations.

The F3 gummies has been tested for different evaluation parameters which found to be within permitted range.

The gummies prepared had a good physical appearance with a good distribution of colour and good taste. Thickness of the gummies were found to be within the limit. Since The gummies average percent deviations

were found to be under the threshold, the formulation passes the weight variation test. The pH of gummies were found to be same as that of the pH of saliva. The drug content of gummy was 93.92%. The gummies, however, were found to be within the permitted range, and the formulation thus passed the various testing.

CONCLUSION:-

One of the innovative novel dosage forms that, if properly developed, will have a significant impact on the pharmaceutical industry is the use of medicated gummies to administer medications to children. These dosage forms promote patient compliance and are well liked by both parents and children while yet retaining good effectiveness & bio availability.

The Gummies were prepared by melt granulation method. The gummies were tested for different evaluation parameters such as physical appearance, thickness, hardness, weight variation, drug content. The gummies tested were found to be within the range for all the evaluation parameter also the technique is simple, economical & time saving. As a result of their many additional benefits, such as patient compliance, convenience & comforts for effective treatment, including low dose, immediate onset of action & economical factor, medicated gummies will be the ideal dosage form for the paediatric patient. They will provide a more effective & creative dosing form.

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