



Formulation And Evaluation Of Oral Ibuprofen-Paracetamol Jelly On Laboratory Scale

Honde Bharat S.^{1*}, Bhalerao Rushikesh D.², Bhandari Sarvesh P.³, Bhongal Mayuri B.⁴, Galhe Samruddhi A.⁵, Belkar Rohini D.⁶, Bagul Siddharth S.⁷

^{1*,2,3,4,5,6,7}Department of Pharmaceutical Chemistry S.V.N.H.T'S College of B.Pharmacy, Shrishivajinagar (Rahuri factory), Tal-Rahuri, Dist-Ahmednagar, MS, India-413706.

***Corresponding Author:** Dr. Honde Bharat Shivaji

***Head,** Department of Pharmaceutical Chemistry, S.V.N.H.T'S College of B. Pharmacy, Shrishivajinagar (Rahuri factory), Tal-Rahuri, Dist-Ahmednagar, MS, India-413706. E. mail I.D.-bharathonde@gmail.com

Article History	Abstract
Received: 13 April 2023 Revised: 27 April 2023 Accepted: 12 May 2023	Oral medicated buprofen paracetamol jellies are best semi solid dosage forms administered through the oral route. Oral medicatedibuprofen paracetamol jellies provide several advantages as pharmaceutical formulations however with some disadvantages like Dysphagia. Oral medicated jellies as a dosage form can be adopted laboratory equipmentfor drug delivery system. Oral solid dosage forms were the most preferred dosage forms for a wide range of populationin elderly and 12 years and above age patient due to they easy to administration. Solving difficulties and Dysphagia problems are the main disadvantages which can minimize as possible. The ultimate purpose for this formulation is to introduce opportunities of providing the oral jelly as a suitable alternative to the readily available solid dosage forms of the same medicament.
CC License CC-BY-NC-SA 4.0	Keywords – Dysphagia, Oral jelly, ibuprofen, paracetamol, administration.

INTRODUCTION:

Jelly is an transparent or translucent non-greasy, semisolid preparations meant for external as well as internal application.^{[1][2][15]} Dysphagia is a medical term originated from the Greek words dys, meaning “difficulty”, and phagia, meaning “to eat”. To avoid dysphagia in any age group persons. The formation and evaluation of jelly is effective in the condition of dysphagia. Convenience of administration and patient compliance are gaining significant importance in the design of dosage forms. Paracetamol and ibuprofen is an orally administered antipyretic and analgesic agent, used in the management of pyretic and analgesic condition. Difficulty in swallowing (dysphagia) is common among all age groups, especially in elderly and pediatrics. Persons suffering dysphagia may get choked when they consume liquid formulations, thus to alleviate such problem liquid formulation of high viscosity were prepared. Formulation of oral ibuprofen Paracetamoljelly. The main advantages in oral jellies possess certain advantages such as improving the bioavailability by reducing first pass effect since it is introduced to the GIT as dissolved in the saliva, in addition to its higher patient acceptance and compliance due to its rheological behavior and its suitability of administration at any time and place without the requirement of water^[6] The jelly dosage form not only overcomes the disadvantages of solids dosage form, but also of liquid dosage forms. The aim of the present study was to improve patient

compliance by development of jelly preparation of an orally administered (Ibuprofen paracetamol jelly) used in treatment of fever and pain and reducing the condition of dysphagia. Apart from that jelly preparation also helps to control over harshness and bitterness of drug. So we can say it as patient friendly dosage form^{[1][2][14]}

EXPERIMENTAL:

MATERIALS AND METHODES:

Sr. No.	Ingredient/Excipient	Each 4 gm Contain	Uses
1	Ibuprofen	150 mg	Analgesic & NSAID (API)
2	Paracetamol	300 mg	Antipyretic & NSAID (API)
3	Gelatin	400 mg	400 mg
4	Sucrose	800 mg	Sweetener and bulk former
5	Sodium Saccharin	0.05 mg	Sweetener
6	Methyl Paraben	0.05 mg	Preservative
7	Glycerine	3-5 ml	Stabilizer
8	Strawberry flavour	Quantity sufficient	Flavouring agent
9	Tartrazine	Quantity sufficient	Colouring agent
10	Water	Quantity sufficient	Solvent

Preparation of oral Ibuprofen Paracetamol jelly:

Clean and sterilize all requirement, should be place in aseptic room. 4gm Gelatin should be accurately weighed then dissolve in 25-30ml volume of distilled water at 95 ° C for 20-30 minute. Make a simple syrup with dissolving a 8gm sucrose into 4-5ml water at 75-80 ° C ,with continuous stirring. Then adding sugar syrup to above mixture at 70-75 ° C ,with continuous stirring. Make a slurry of API by mixing 3-5ml glycerin into ibuprofen and paracetamol. Then adding slurry with preservative, stabilizer, flavoring agent, coloring agent etc, with continuous stirring.^{[1][6][8][15]}

RESULT AND DISCUSSION:

Challenges in the Formulation of the Oral Jellies

Several challenges occurred in the formulation of the oral jellies, these may include:

1. The amount of drug/Drug contain

In the formulation of oral ibuprofen paracetamol jellies the amount of drug in a single dose difficult to measure depending on amount of active drug there are three challenges including taste masking of the active ingredient, jelly size and mouth feel or grittiness.^{[1][8][9]}

2. Taste masking:- In oral administration taste masking is the important parameter, the desirable taste is the better choice for pediatrics .

Types of taste - 1. Bitter, 2. Sweet, 3. Salt, 4. Sour.

Reduction bitter taste of drugs

Maintain the pH as pH of saliva and uses flavors and sweeteners.^{[3][5][10]}

3. Jelly size:-

The size of jellies is between 5mm-8mm, which can easy to eat in any age group.^{[1][9][14]}

4. Mouth feel

The Oral medicated jellies should not disintegrate into the oral cavity.

Using flavors and cooling agents like menthol improve the mouth feel.^{[3][5][7][10]}

5. Aqueous solubility

The aqueous solubility of drug can causes many challenges like depression in freezing point of oral jellies. which they form eutectic mixtures.^{[1][11]}

6. The drug property

Certain properties such as crystal morphology, particle size, solubility and bulk density could affect the jelly performance.^[9]

7. Environmental Sensitivity

Oral jellies are sensitive to environmental temperature and humidity, for this reason special packaging should be applied. Melting of jellies can be avoided by special store in freezer or deep freeze.^{[1][2][8][15]}

Evaluation of oral ibuprofen paracetamol jelly.

Following studies were carried out for evaluation of oral ibuprofen paracetamol jelly.

1.General appearance

Texture and clarity of the oral jellies was evaluated in terms of stickiness and grittiness by mildly rubbing the gel between two fingers. Consistency and odour were also evaluated by physical observation. Color is observed by general appearance.^[1]

2.Disintegration time

The disintegration time of the jelly can be determined by the disintegration test apparatus with using Phosphate buffer.^{[1][13]}

3.Viscosity

Viscosity had been measured using digital viscometer. The spindle no. 4 was used for determination of viscosity NonNewtonian fluids.^{[1][11][13]}

4.Stickiness

It is determined by rubbing the jelly between two fingers and then stickiness is checked visually.^[8]

5. pH

It is determined by the electronic pH meter. The pH of the oral jellies is between 6.5-7.^{[1][15]}

6. Sterility study:-

These studies are important parameter for determining the microbial profile of jellies. As jellies are more prone to microbial growth due to presence of water. These study done by direct inoculation method of culture media.^[4]

EVALUATION :-

Sr.No.	Evaluation	Observation
1	General appearance	
	Colour	Red
	Teast	Sweet
	Odour	Characteristic (aromatic)
	Shape	Rectangular
	Average size	1.5 cm
	Texture	smooth
	Clarity	Partially transparent
2	Aqueous Solubility	Good soluble
3	Disintegration time	2 minute.
4	Viscosity	321480 cP
5	Stickiness	Non sticky
6	pH	6.70 ±1
7	Sterility study	Sterile

CONCLUSION:-

The formulation and evaluation of an oral ibuprofen paracetamol jelly give a suitable drug delivery system. It making it a good substitute over the readily dosage forms for administration to dysphagic populations. Further studies are required to discover the various applications, good of this dosage form and to determine the possible ways to improve its stability.

ACKNOWLEDGEMENT

The Principal and President are thankful S.V.N.H.T'S College of B. Pharmacy, Shrishivajinagar (Rahuri factory), Tal-Rahuri, Dist-Ahmednagar for providing laboratory facilities.

REFERENCE

1. Shekhar Priyanshu, Joshi Ankur, Malviya Sapna and Kharia Anil ,Formulation Development and Evaluation of Pediatric Oral Medicated Jelly of Paracetamol and Ibuprofen Modern Institute of Pharmaceutical Sciences, Indore 453111.

2. Ashwini D. Darade and Atish S. Mundada, Oral medicated jellies as a emerging platform for oral drug delivery in pediatrics, World journal of Pharmaceutical Research .
3. Bhalerao K, Gambhire S, Singh S. Taste masking to improve compliance". Int.Dosage form Design parameter (volume II) Advances in Pharmaceutical Product Development and Research 2018, Pages 467-519.
4. Thoke, S.B., Gayke, A., Dengale, R., Patil, P. and Sharma, Y., "Review on: tastemasking approaches and evaluation of taste masking", International Journal of Pharmaceutical Sciences, 2012; 4(2): 1895-1907.
5. Yadav, C., Tangri, S. and Yadav, R., "A review: recent advancement in formulationof oral medicated jelly", World Journal of Pharmacy and Pharmaceutical Sciences, 2018; 7(7): 416-427.
6. Tripathi, A., Parmar, D., Patel, U., Patel, G., Daslaniya, D. and Bhimani, B., "Tastemasking: a novel approach for bitter and obnoxious drugs", JPSBR, 2011; 1(3): 36-142.
7. Preparation and Comparitive Studies of Orange-Aloevera-Gourd Based Jelly International Journal of Recent Scientific ResearchVol. 10, Issue, 05(G), pp. 32600-32602, May, 2019.
8. Dubey, M. and Sheth, Z., "Design and development of oral medicated jelly of Palonosetron hydrochloride". Indian journal of research, 2015; 4(6).
9. Sharma, V. and Chopra, H., "Role of taste and taste masking of bitter drugs inpharmaceutical industries an overview". Int J Pharm Pharm Sci, 2010; 2(4): 123-5.
10. Tabak, L.A., Levine, M.J., Mandel, I.D. and Ellison, S.A., "Role of salivary mucinosis the protection of the oral cavity". Journal of Oral Pathology & Medicine, 1982; 11(1):1-17.
11. Roy, G.M., "Taste masking in oral pharmaceuticals", Pharmaceutical technology, 1994; 18(4): 84-84.
12. Imai, K., "Alendronate sodium hydrate (oral jelly) for the treatment of osteoporosis:review of a novel, easy to swallow formulation". Clinical interventions in aging, 2013; 8: 681.
13. Yadav, C., Tangri, S. and Yadav, R., "A review: recent advancement in formulationof oral medicated jelly", World journal of pharmacy and pharmaceutical sciences, 2018; 7(7): 416-427.
14. Godhwani, T., Chhajed, M., Chhajed, A. and Tiwari, D., "Formulation developmentand evaluation of unit moulded semisolid jelly for oral administration as a calciumsupplement". World J. Pharm. res, 2012; 1: 626-634.
15. Sagar Bashyal, Ibuprofen and Its Different Analytical And Manufacturing Methods: A Review, Asian J Pharm Clin Res, Vol 11, Issue 7, 2018, 25-29.
16. Rabia Bushra and Nousheen Aslam, An Overview of Clinical Pharmacology of Ibuprofen, Oman Medical Journal 2010, Volume 25, Issue 3, July 2010.