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Research

Formulation, Development, And Evaluation Of Paracetamol Ibuprofen Oral Medicated Jelly

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Abstract

The objectives of the present investigation were to formulate and evaluate of Medicated oral jelly containing Paracetamol and Ibuprofen for the treatment of mild to moderate pain. Ibuprofen + Paracetamol is used for pain relief and fever. It relieves pain in condition like headache, mild migraine, muscle pain, dental pain, rheumatoid arthritis, period pain osteoarthritis or painful menses. Jellies are prepared by heating and congealing methods by dispersing gelling agents in water and evaluated for their physicochemical parameters like appearance, stickiness, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity. All batches (F1-F2) of medicated jelly showed acceptable and comparable appearance, pH, viscosity, Spreadability, stability studies, drug release, and content uniformity. The viscosity range was found to be 53305 to 61731cps. The drug content of Paracetamol of F1 & F2 96.06% and 98.15% and drug content of Ibuprofen of F1 & F2 was found 96.1% and 95.7%.

Keywords: Medicated Jelly, Paracetamol, Ibuprofen.

INTRODUCTION

Patients are usually comfortable with the oral drug delivery system since it is non-invasive and usually offers a low cost of treatment. Also, the safety, efficacy, and cost-effectiveness of the oral drug delivery system enhance its patient compliance[1]. Many medications are taken orally because they are intended to have a systemic effect, reaching different parts of the body via the bloodstream Current pediatric formulations have so many drawbacks. Most of the pediatric formulations available in the market are tablets, capsules, syrups, solutions, and

drops. For liquid formulations dose volume is a major consideration. Only dose volume less than 5ml is recommended for children under five years and less than 10ml is recommended for children of five years and older.

Stability issues of liquid formulations are another concern. The drug is in solution or suspension form and easily degrades. We know that the API of the majority of the drugs is bitter in taste. When it comes in contact with our tongue it becomes unacceptable to any age group and very intolerable, especially for children.

To mask this bitter taste high concentrations of sweeteners are used, jellies can overcome this problem since jellies are having high viscosity.[1] This property can be utilized for taste masking, solving stability issues, and enhancing sustained release. As these jellies have an eye-catching appearance, and pleasant taste, and are easy to handle, everyone prefers jelly over oral liquids or tablets. Chewable dosage forms are more convenient in the administration of drugs for dysphagia patients and offer ease of handling compared to liquid and powder formulations. The chewable formulation has a high drug-carrying capacity and requires less amount of super disintegrants. By systemic administration of drug through the oral mucosa, it has the ability to overcome the difficulties of short-lived action and differences in the release of drug and retaining times. Oral medicated jelly avoids first-pass metabolism[4].

Jelly

As per FSSA, Fruit Jelly means the product prepared by boiling fruit juice or fruit(s) of sound quality, with or without water, expressing and straining the juice, adding nutritive sweeteners, and concentrating to such a consistency that gelatinization takes place on cooling. The product shall not be syrupy, sticky, or gummy and shall be clear, sparkling, and transparent. Jelly is also considered a dessert in many parts of the world. This kind of dessert was first recorded as jelly by Hannah Glasse in her 18th-century book *The Art of Cookery.* appearing in a layer of trifle.

Method of preparation of paracetamol ibuprofen oral jelly

Calibration curve of paracetamol

Preparation of stock solution

A stock solution of the drug (1mg/ml) is prepared by dissolving 100 mg of paracetamol in a 100 ml solution of methanol and phosphate buffer ph 6.8 (in 1:3 ratio) in a 100 ml volumetric flask (to get 1000 µg/ml drug solutions) with vigorous shaking and further sonicated for about 10 minutes. It was labeled as the stock solution.

Preparation of Working standard solution

From the stock solution, 10 ml was pipette out & diluted to 100ml with 6.8 pH phosphate buffer in a volumetric flask. The resultant solution had a concentration of 100µg/ml & was labeled as a working standard solution.

Dilutions

Take the respective samples (0.2ml,0.4ml, 0.6ml, 0.8ml, 1ml, 1.2ml, 1.4ml, 1.6ml, 1.8ml, 2ml, 2.2ml, 2.4ml) in each test tube, add phosphate buffer 6.8 to make total volume of 10 ml to produce (2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24µg/ml).

Determination of absorption maxima

A UV absorption maximum was determined by scanning a 10µg/ml solution of paracetamol in phosphate buffer 6.8, between 200-400 nm by using a UV-visible spectrophotometer.

Calibration curve of ibuprofen

Preparation of stock solution

Stock solution of the drug (1mg/ml) is prepared by dissolving 100 mg of ibuprofen in 100 ml solution of methanol and phosphate buffer ph 6.8 (in 1:3 ratio) in 100 ml volumetric flask (to get 1000 µg/ml drug solutions) with vigorous shaking and further sonicated for about 10 minutes. It was labeled as the stock solution.

Preparation of Working standard solution

From the stock solution, 10 ml was pipette out & diluted to 100ml with 6.8 pH phosphate buffer in a volumetric flask. The resultant solution had a concentration of 100µg/ml & was labeled as a working standard solution.

Dilutions

Take the respective samples (0.2ml,0.4ml, 0.6ml, 0.8ml, 1ml, 1.2ml, 1.4ml, 1.6ml, 1.8ml, 2ml, 2.2ml, 2.4ml) in each test tube, add phosphate buffer 6.8 to make total volume of 10 ml to produce (2, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24µg/ml).

Determination of absorption maxima

A UV absorption maximum was determined by scanning a 10µg/ml solution of paracetamol in phosphate buffer 6.8, between 200-400 nm by using a UV-visible spectrophotometer.

Preparation of medicated pediatric oral jelly

1. Medicated jelly is prepared by heating & congealing method. Jelly base consisting of sucrose, gelatine & other excipients are added and heated until dissolved then allowed to cool to form a jelly.
2. Weigh all the required ingredients of the formulation accurately.
3. Sucrose syrup was prepared by adding sucrose to water & is heated until it is dissolved, then citric acid is added to prevent crystallization of sugar
4. In another beaker, Gelatine was soaked in the required quantity of water to facilitate its hydration, and then it is added to the above mixture & heated until completely dissolved.
5. Add the weighed Pectin and dissolve it completely
6. Then drug complex is prepared, sodium benzoate was dissolved in an appropriate vehicle, & added to the above mixture with stirring[9].
7. After that sodium citrate was added with continuous stirring to maintain pH.
8. The solution is mixed thoroughly and uniformly and & heated until completely dissolved.
9. Then colour, and flavouring agents were added to the above mixture & mixed thoroughly.
10. The weight of the jelly was monitored during the preparation & the final weight was adjusted to 10g using distilled water, mixed, These whole solutions transfer into moulds which are coated with glycerine and then allow for cooling and settling, it was kept for 1 hrs at 10-15ºC. The formulation of medicated jelly was given.

Table 1: Formulation of Paracetamol Ibuprofen Pediactric Oral Jelly

SLNO.	INGREDIENTS	F1	F2	F3	F4	F5
1.	PARACETAMOL	0.325g	0.325g	0.325g	0.325g	0.325g
2.	IBUPROFEN	0.2g	0.2g	0.2g	0.2g	0.2g
3.	SUCROSE	5g	5g	5g	5g	5g
4.	GELATIN	2g	3g	3g	4g	4.5g
5.	PECTIN	-	-	0.05g	0.05g	0.05g
6.	CITRIC ACID	0.03g	0.03g	0.03g	0.03g	0.03g
7.	SODIUM CITRATE	0.08g	0.08g	0.08g	0.08g	0.08g
8.	SODIUM BENZOATE	0.1g	0.1g	0.1g	0.1g	0.1g
9.	WATER	Q.S	Q.S	Q.S	Q.S	Q.S
10.	COLOURING AGENT	Q.S	Q.S	Q.S	Q.S	Q.S
11.	FLAVOURING AGENT	Q.S	Q.S	Q.S	Q.S	Q.S
	TOTAL WEIGHT	10g	10g	10g	10g	10g

Each jelly weighs 5grams and each jelly contains 0.162mg dose of Paracetamol and 0.1mg dose of Ibuprofen.

Fig 1: Optimized Jelly formulation

Evaluation Parameters

Physical appearance: The medicated jelly was examined for physical appearance in terms of clarity, texture, and consistency.

Stickiness And Grittiness: The texture of the medicated jelly in terms of stickiness and grittiness had been evaluated by visual inspection of the product after mildly rubbing the jelly sample between two fingers.

pH: The pH of all the jelly was determined using a digital pH meter. 0.5 gm of the weighed formulation was dispersed in 50 ml of distilled water and the pH was noted.

Syneresis: Syneresis is defined as the contraction and separation of water from gel upon storage. One of the major causes of it is using a lesser concentration of the gelling agent. Low acylated guar gum gels are mostly prone to syneresis

Content Uniformity: The content uniformity test is to ensure that every dosage form contains an equal amount of drug substance. Jelly from each formulation was taken, crushed, and mixed. From the mixture drug equivalent of the mixture was extracted thoroughly with suitable media. The amount of drug present in each extract was determined using a suitable analytical method.

An In-Vitro Dissolution Study

Dissolution method for combination of ibuprofen and paracetamol tablets using UV spectrophotometric method. The analytical method was developed by UV spectrophotometry using the absorbance ratio method which involves the measurement of absorbance at two wavelengths 243 nm as the λmax of ibuprofen and wavelengths 252 nm as the λmax of paracetamol and 239 nm as an isosbestic point. The study was conducted using buffer pH 7.2 as dissolution medium at 37±0.5 °C, using USP apparatus II(USP basket apparatus) at a stirring rate of 75 rpm for 1 hr. 5 ml of the sample should be withdrawn after 10, 20, 30, 40, 50, 60, 90,120 min and sink condition is maintained by replacing fresh media. The sample was determined for drug content using a UV spectrophotometer[11].

Drug Excipient Compatibility Studies By Fourier Transform Infrared Spectroscopy (FT-IR)

The compatibility between drug (paracetamol and ibuprofen) and the excipients used was examined using FTIR spectroscopy. In the FTIR spectroscopy technique, significant changes in the shape and position of the absorbance bands are analysed[16]. It analyzes significant changes in the shape and position of the absorbance bands to show the assumption of different functional groups of present and subsequent molecules.

Weight Variation

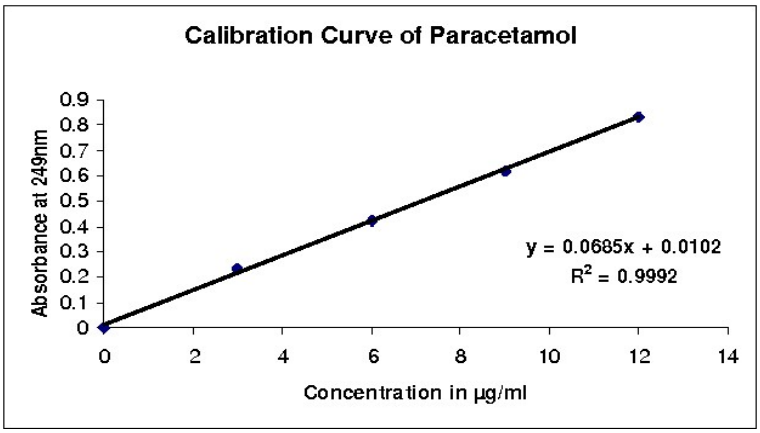
About twenty medicated jellies were taken & their individual weight was determined using an analytical balance. Average weight & %weight variation was calculated.

RESULT AND DISCUSSIONS

Standard calibration curve of paracetamol

Table 2: Calibration curve data of Paracetamol in 6.8pH buffer

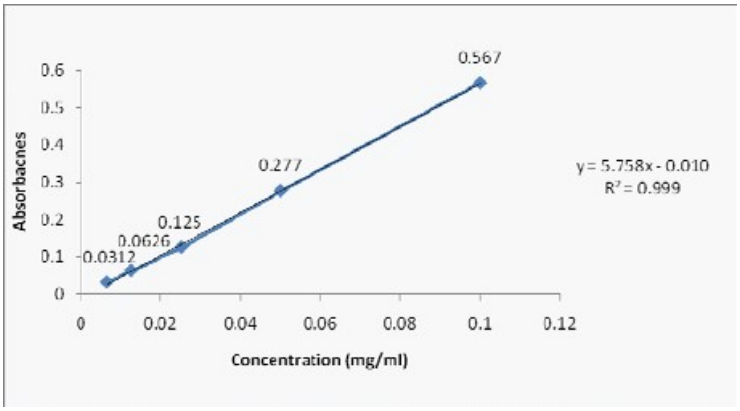
Sno	Concentration ((µg/Ml))	Absorbance
1.	1	0.130
2.	2	0.282
3.	4	0.375
4.	6	0.487
5.	8	0.585



Standard calibration curve of ibuprofen

Table 3: Calibration curve data of Ibuprofen in 6.8pH buffer.

SNO	CONCENTRATIONS	ABSORBANCE
1	1	0.063
2	2	0.106
3	3	0.130
4	4	0.177
5	5	0.200



Evaluation results of medicated jelly

Physical Appearance

The physical appearance including clarity, homogeneity as well as other features of the prepared Paracetamol Ibuprofen jellies were observed that showed all jellies were clear, red in color, had semisolid consistency, homogenous, and have a pleasant fruity aroma.

Table 4: Physical Appearance Test Parameter

SNO.	Test Parameters	F1	F2	F3	F4	F5
1.	Clarity	C	C	C	C	C
2.	Colour	R	R	R	R	R
3.	Odour	PL	PL	PL	PL	PL
4.	Particulate matter	N	N	N	N	N
5.	Stickiness	S	SS	SS	NS	NS

C: Clear, R: Red, PL: Pleasant, N: No, S: Sticky, SS: Slight Sticky, NS: Non-Sticky

pH: pH of the F5 formulation was found to be 6.58±6.83. The pH of the formulation influences the taste and stability of oral jellies. Therefore, a minimum quantity of Sodium Citrate was added just to maintain the pH.

Syneresis: Jelly experiences syneresis or de-swelling due to the release of liquid, resulting in shrinkage of gels and reduced quality. Syneresis was more pronounced in the gels, where lower. the concentration of gelling agent was employed. It was observed after 24 h of jelly preparation,the formulations F1, F2, and F3 showed syneresis at room temperature (25°C ± 5°C). Syneresis was not noticed at room temperature by Formulations F4 and F5 probably due to the binding of free water by co-solute. In the preformulation studies, jellies containing gelatin and pectin combination did not show syneresis. Hence, in order to reduce syneresis of paracetamol ibuprofen jellies, pectin was used as co-solute.

Table 5: Syneresis of Formulations

Parameters	F1	F2	F3	F4	F5
Syneresis	Yes	Yes	Yes	No	No

Weight variation: The f4-f5 formulation showed a weight variation of ±1.9 which is within the limit i.e ±5%.

Fig 2: weight of the jelly before forming the jelly

Content Uniformity: The drug content was found in the range of 97.63% ±0.63%–99.23% ±0.66%, which conformed with the pharmacopoeial specification of 95-105%.

Fourier Transform Infrared Spectroscopy (FT-IR): Shimadzu Fourier-transform infrared spectrophotometer was used to perform the compatibility studies. Absorption bands of pure drug paracetamol and ibuprofen are as follows: It was found that drug & excipients were compatible.

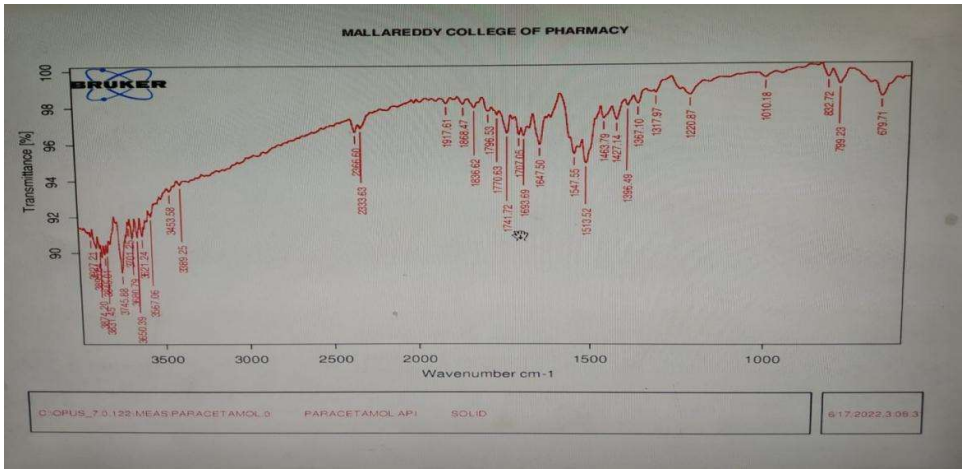


Fig 3: Compatibility Studies

FTIR of Paracetamol Standard

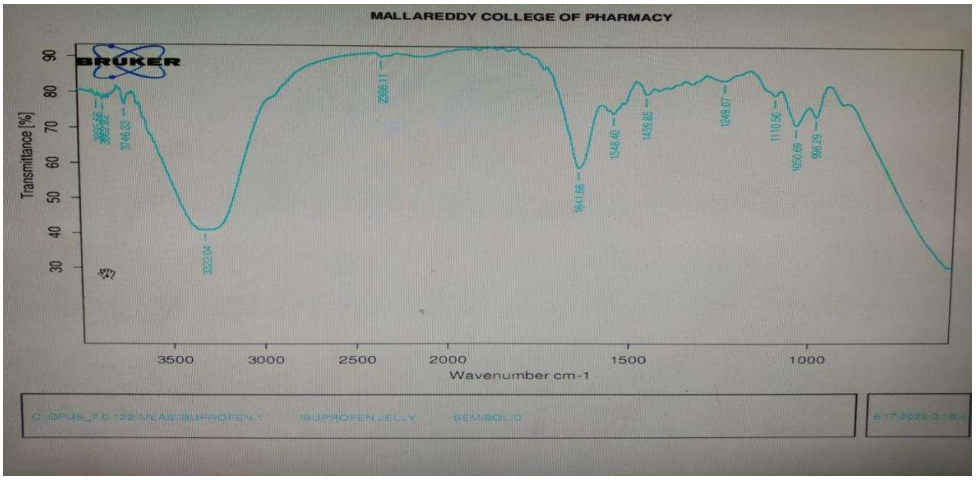


Fig 4: FTIR of Standard Ibuprofen

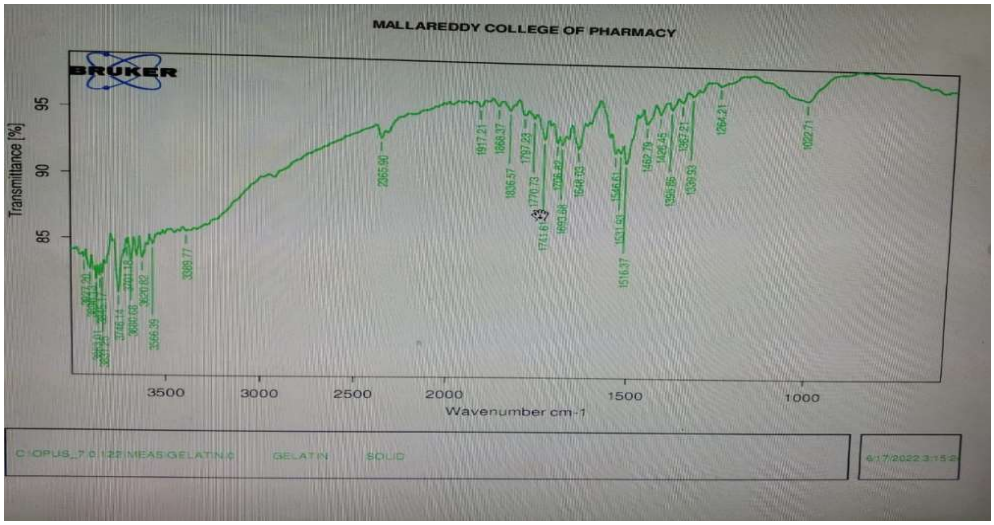


Fig 5: FTIR of Gelatin Standard

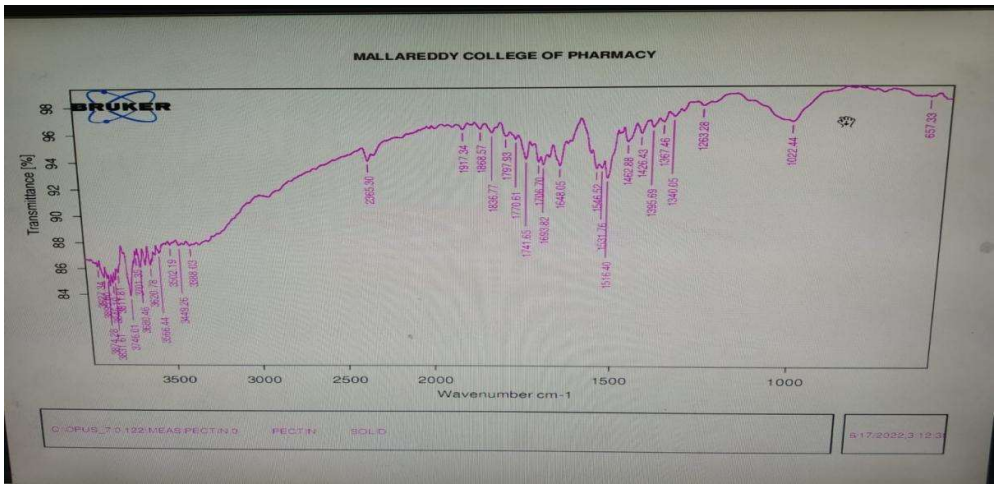


Fig 6: FTIR of Pectin Standard

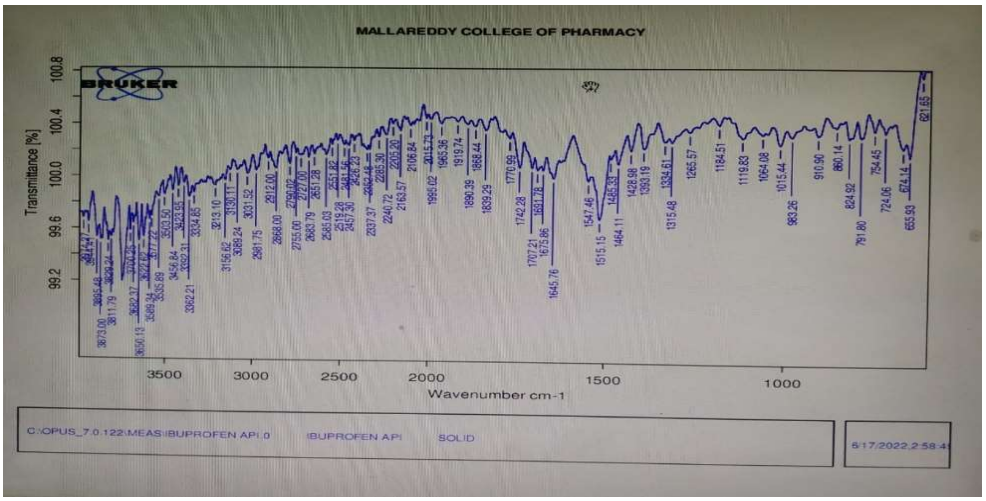


Fig 7: FTIR of paracetamol+ibuprofen+gelatin+pectin+excipients

CONCLUSION

With respect to the pediatric age group, medicated jellies have the potential to evolve as one of the most popular dosage forms. Its unique properties help us to improve better patient compliance with respect to pediatric groups. It was also able to provide prominent therapeutic effectiveness by early onset of action as having quick absorption and dissolution of the drug. By controlling the viscosity of jelling agent, the rate of drug release and drug plasma level can be controlled. In the present study, medicated Pediatric Paracetamol Ibuprofen Oral Jelly was prepared successfully using Gelatin and Pectin. Among various formulations, F4 and F5 formulation has not shown signs of syneresis after 24hr of preparation whereas other formulations were prone to syneresis due to lesser concentration of the gelling agent. Invitro dissolution study results of all formulations show immediate release and it varied according to the concentration of polymer. Percentage Drug content of F5 formulation was highest i.e, 99.30±0.51. In FTIR spectra there is no disappearance of peak present in the drug and physical mixture it shows the compatibility of drug and polymer. The result of Physico-chemical parameters such as pH, appearance, and viscosity showed all formulations were within the standard limit and compared to other F5 is considered as best in their characteristics.

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