WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 13, Issue 11, 1522-1532. Research Article ISSN 2277–7105

RESEARCH ARTICLE: FORMULATION AND EVALUATION OF FLOATING TABLET

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Article Received on
13 April 2024,

Revised on 03 May 2024,
Accepted on 22 May 2024

DOI: 10.20959/wjpr202411-32632

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ABSTRACT

Floating matrix tablets were developed to prolong gastric residence time and increase drug absorption further increasing the bioavailability. Various forms of gastro retentive drug delivery system, such as floating and non- floating. Floating tablets was formulated to increase gastric residence and there by improve its therapeutic efficacy. By using different polymers such as carbopol, guargum, HPMC K100, HPMCK4 etc. By using direct compression method. Formulated F1 to F10 batches tablets showed satisfactory results for various post compression evaluation parameters like thickness, hardness, weight variation, floating lag time, total floating time, content uniformity and invitro drug release. Formulation batches were perform in that all batches were passes to preformulation study and post formulation study was F6 batch are obtimise to passes all parameter's.

KEYWORDS: Floating Drug Delivery System, Floating tablets, GRDDS.

1. INTRODUCTION

In 1968, Davis First Inventor of Floating drug delivery system. The oral route is considered as the most favourable route of drug delivery.[1]

Gastric emptying of dosage forms is an extremely variable process and ability to prolong and control emptying time is a valuable asset for dosage forms, which reside in the stomach for a longer period of time than conventional dosage forms.[2]

Unpredictable gastric residence time (GRT) of a controlled release dosage form leads to interest in targeting and retaining the dosage form in the stomach for a prolonged period of

time. Thus Retention of drug delivery systems in the stomach prolongs overall gastrointestinal transit time and improves the oral bioavailability of the drugs that are having site-specific absorption from the stomach or upper part of the small intestine.[3]

- **Stomach**

The main function of stomach is to store food temporarily grind it and then release it gradually into the duodenum.

Gastro intestinal motility is based onfasted and fed state of the stomach, two distinct patterns of gastrointestinal (GI) motility and secretions have been identified.

Phase I

It is an inactivity period lasting from 30 to 60min with no contractions and is characterized by absence of secretory, electrical andcontractile activity. It is also called basal phase.

Phase II

It is also called as pre-burst phase it consists of intermediate active contractions that gradually increase in intensity and frequency as the phaseprogresses and it lasts about 20 to 40 min.

Phase III

This is a short period of intense distal and proximal gastric contractions this is 4-5 contractions per min due to this contraction all the undigested material is cleared out of the stomach down the small intestine. It is alsoknown as “house-keeper waves”.

Phase IV

This is the short period of about 0 to 5 min and contractions disperate between the last part of the phase III and quiescence of phase I.[4]

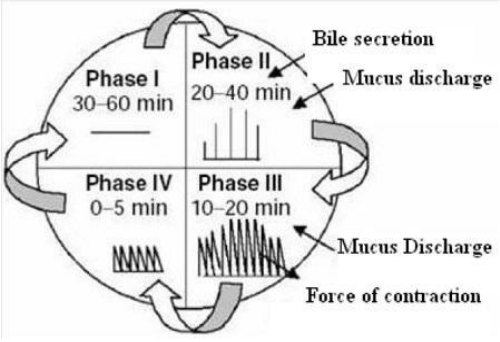

Figure 1: Schematic Representation of Interdigestive Motility.

1.1 FORMULATION OF FLOATING TABLETS[5]

Amitriptyline hydrochloride, HPMC K4M, HPMC K100M, Carbopol 934, Xanthum gum, Karaya gum, Gaur gum. Microcrystalline cellulose and other ingredients were passed through sieve no. 18 separately. The drug was then mixed with the polymer and other ingredients. Magnesium Stearate was uniformly mixed with the above mixture and then directly compressed in a single punch tablet compression machine with 3 mm. The composition of all formulation is given in table.

Table 1: Composition of Formulations F1 to F 10.

Name of Ingredient (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Amitriptyline Hydrochloride	10	10	10	10	10	10	10	10	10	10
HPMC K100	20	30	30	_	_	20	10	5	_	_
HPMC K4	_	_	_	20	_	_	_	_	20	_
Carbopol 934	20	_	_	_	30	20	10	5	5	20
Xanthum gum	_	_	20	_	5	_	_	_	_	10
Gaur gum	_	15	_	_	_	_	_	_	_	_
Karaya gum	_	_	_	20	_	_	_	_	_	_
Citric acid	_	_	_	_	_	_	_	_	10	_
Magnesium stearate	2	2	2	2	2	2	2	3	3	2
Microcrystalline cellulose	12	2	2	10	8	12	22	_	_	8
Talc	11	16	10	11	30	11	21	52	27	25
Sodium bicarbonate	21	21	21	21	21	21	21	21	21	21
Polyvinylpyrrolidone K30	4	4	4	4	4	4	4	4	4	4
Total weight of tablet (mg)	100	100	100	100	100	100	100	100	100	100

1.2 ANALYTICAL CHARACTERIZATON OF DRUG SAMPLE

Scanning of Amitriptaline Hydrochloride in 0.1N Hydrochloride acid buffer of pH 1.2

The solution containing 100 µg/ml of Amitriptaline Hydrochloride in 0.1 N Hydrochloride acid buffer of pH 1.2 was scanned over range of 200-400nm against 0.1N Hydrochloride acid buffer pH 1.2 as a blank using thermo double beam UV spectrophotometer. The & max was compared with the reported value.

Preparation of standard calibration curve of Amitriptaline Hydrochloride

The calibration curve of Amitriptaline Hydrochloride was carried out in Hydrochloric acid buffer pH 1.2, 100 mg of drug Amitriptaline Hydrochloride was dissolved in 0.1 N Hydrochloride Acid Buffer of pH 1.2 and volume was makeup to 100ml and dilutions were made as 2, 4, 6, 8, 10 µg/ml and absorbance was taken at 239nm.

Table 7: Calibration curve of Amitriptyline Hydrochloride.

Sr.no.	Concentration (ug/ml)	Absorbance (λ=239)
1	2	0.094
2	4	0.174
3	6	0.251
4	8	0.344
5	10	0.425

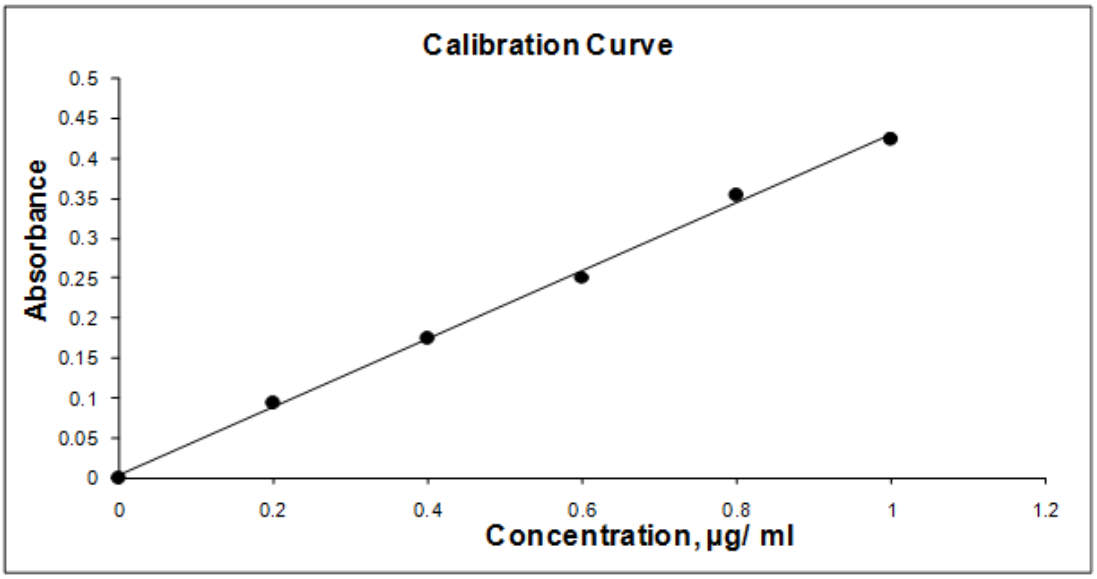

Figure 2: Standard Calibration Curve of Amitriptyline Hydrochloride in pH 1.2.

0.1 N HCL Dissolution Medium

Correlation coefficient (R^2) = 0.9990

Equation of regressed line y =0.0415x+0.009

Where,

X = Value for concentration

Y = Regressed value of absorbance

1.3 PHYSICAL PROPERTIES OF POWDER

Different formulation were prepared with different level addition of HPMC K100, HPMC K4, Carbopol 934, Gaur gum, Xanthum gum, Karaya gum, PVP K30, Magnesium stearate, Sodium bicarbonate, Talc, MCC.

Table 2: Pre-compression parameter of preliminary Batches of Amitriptaline Hydrochloride.

Batch No	Angle of repose (degree)	Bulk density (g/cm^3)	Tapped density (g/cm^3)	% compressibility (%)	Hausner's ratio
F1	39.16 ± 49.9	0.27 ± 0.06	0.426 ± 0.06	13.3± 6.3	1.12 ±0.06
F2	30.8 ± 36.6	0.26 ±0.06	0.50 ± 0.06	14.3± 25.4	1.21± 0.16
F3	33.33 ± 11.4	0.26 ± 0.11	0.46 ± 0.01	13±11	1.16± 0.16
F4	36.4 ± 56.95	0.22 ± 0.12	0.58± 0.01	20.3±6.3	1.96±0.05
F5	30 ± 48.7	0.41±0.11	0.46± 0.11	17.6±6.3	1.23±0.63
F6	35.4 ±47.18	0.30 ± 0.12	0.38± 0.11	10.3±6.3	1.106±0.06
F7	40.3 ± 16.80	0.25 ±0.11	0.51± 0.11	21± 11	1.5±1.1
F8	38.0 ± 42.89	0.31 ± 0.06	0.51± 0.06	12.6±6.3	1.8±1.1
F9	37.1 ± 63.30	0.32 ±0.12	0.50± 0.06	13.6± 12.7	0.84±6.16
F10	32 ± 12.11	0.31±0.06	0.50± 0.06	12.3±6.3	0.96±0.05

The result of bulk density and tapped density were mentioned in an above table. The bulk density and tapped density values were lies in between **0.22 ± 0.12 to 0.32 ±0.12** and **0.38± 0.11 to 0.58± 0.01** respectively ie. less than 1.2, indicates good packing.

The values of % compressibility, Hausner's ratio and angle of repose were lies in between **12.3±6.3 to 21± 11**, **0.84±6.16 to 1.96±0.05** and **30 ± 48.7** to **40.3 ± 16.80** respectively indicates acceptable flow property and also good packing ability. Therefore, the tablet blend might be used for the preparation of controlled released floating effervescent tablets.

1.4 DRUG INTERACTION STUDIES (COMPATIBILITY STUDIES)

1.4.1 FT-IR SPECTROSCOPY

It's important to check any kind of interaction between drug candidate and polymer. The polymers which are to be incorporated into formulation should be compatible with the drug. This compatibility study or interaction study was done using Fourier transformed infrared spectroscopy.

Table 3: Interpreatation of FTIRPeaks present In Amitriptyline hydrochloride and complex mixture of drug and excipients.

Functional group present in Amitriptyline hydrochloride	IR Peacks of Amitriptyline hydrochloride (cm^{-1})	IR Peaks of Mixture of Drug and Excipients (cm^{-1})
Benzen	2435.23	2440.06
Cyclobenzen	3473.95	3378.47
C-C	1255.71	1267.29
C-N	1167.95	1350.2
C=C	1693.57	1658.85

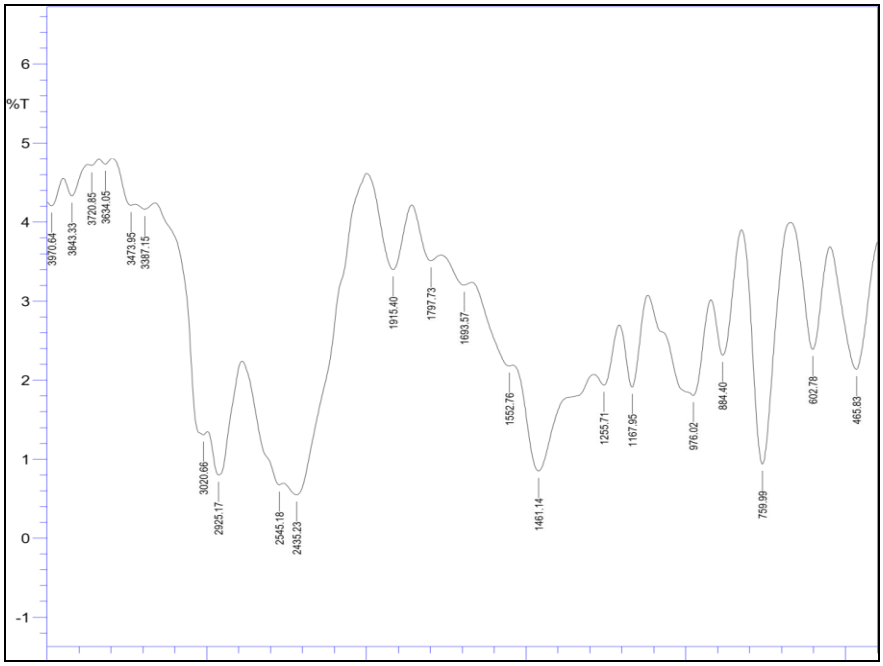

Figure 3: IR Spectra of Amitriptyline hydrochloride pure drug.

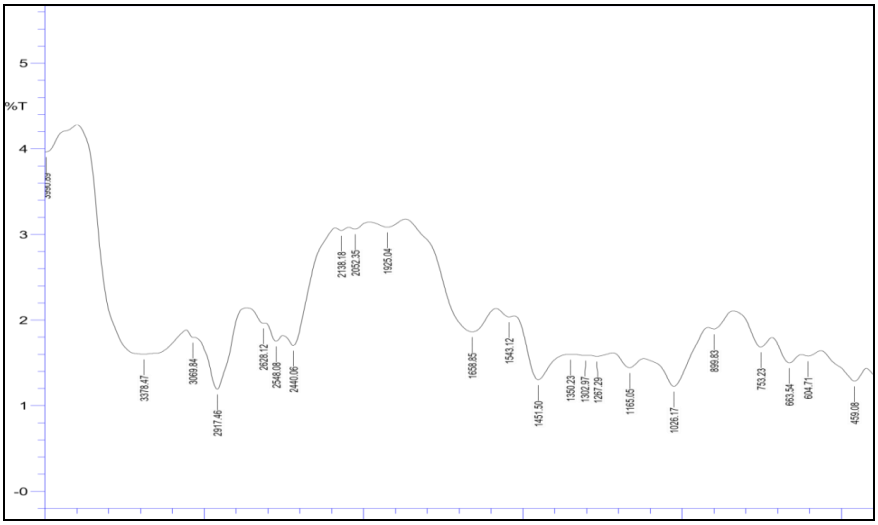

Figure 4: IR Spectra of Mixture of drug and exicipients.

The result shows that there was no incompatibility seen in between drug Amitriptaline hydrochloride and polymers, as there was no significant change in the pattern of peaks of optimized batch of microspheres with the pure drug.

2. MATERIALS AND METHOD

Different formulation were prepared with different level addition of HPMC K100, HPMC K4, Carbopol 934, Gaur gum, Xanthum gum, Karaya gum, PVP K30, Magnesium stearate, Sodium bicarbonate, Talc, MCC drug amitripaline hydrochloride as a antidepressant, by using direct compression method.

3. RESULT

3. 1 FORMULATION STUDIES

3.1.1 EVALUATION OF TABLET

Table 4: Post- Compression parameter of preliminary Batches of Amitriptaline Hydrochloride.

Batch No	Hardness (Kg/cm^2)	Thickness (mm)	Weight variation (mg)	Swelling index (%)	Floating lag time (sec)	Floating time(hr)	Friability (%)
F1	3.30±0.27	0.31±0.05	Pass	103±66.91	31.60±6.41	24	0.43±1.6
F2	3.31±0.21	0.31±0.06	Pass	208±85.44	12.27±0.47	24	0.7±1.1
F3	3.50±0.24	0.31±0.12	Pass	Discard	31.23±11.2	24	0.46±1.6
F4	3.33±0.21	0.32±0.11	Pass	Discard	178.21±212	24	0.13±0.1
F5	3.35±0.21	0.31±0.12	Pass	164 ±6.35	60.46±0.16	24	0.36±0.1
F6	3.32±0.21	0.30±0.06	Pass	85 ±0.76	60.24±0.28	24	0.42±1.5
F7	3.32±0.24	0.31±0.11	Pass	158.6±254	59.19±6.44	24	0.61±0.6
F8	3.25±0.14	0.31±0.12	Pass	128 ±6.35	60.33± 0.11	24	0.36±0.1
F9	3.33±0.21	0.31±0.05	Pass	121±181.7	35.33±6.25	24	0.57±0.2
F10	3.32±0.18	0.31±0.05	Pass	226±11	31.23±11.7	24	0.45±0.25

- Hardness values for all formulation were ranged from **3.25±0.145 to 3.50±0.244 kg/cm³** which indicates good mechanical strength of the tablet.
- Friability values for all formulations were in the range of **0.13±0.1 to 0.7±1.1 %**, which is less than 0.1%.
- The thickness of all tablets was in the range of **0.31±0.05 to 0.32±0.11 mm**, which was as desired.
- The swelling index of all tablet was in the range of **85 ±0.76 to 226±11 %,** which was obtain at standard range.

3.2. DRUG CONTENT UNIFORMITY

The assay values for the determination of content uniformity of the all formulations were within the range of 1.45 to 54.8 mg/100ml.

Table 5: Drug content uniformity.

Batch code	Labelled amount of drug(mg) in each table (X)	Drug content (mg/100ml)
F1	10	9.49
F2	10	11.8
F3	10	54.8
F4	10	7.71
F5	10	1.42
F6	10	7.61

F7	10	7.73
F8	10	11.1
F9	10	10
F10	10	2.19

3.3. FLOATING PROPERTY STUDY

- From Table no 10 it was observed that the floating lag time of formulation **F1(31.60±6.41), F9(35.33±6.25)** show lower floating lag time and had low floating time because lower viscosity of **HPMC K4 M** and **carbopol 934** both cambination of polymer.
- **F6(60.24±0.28)** and **F7(59.19±6.44)** show satisfactory floating lag time and being the because satisfactory viscosity of **HPMC K4M** and **carbopol 934** that equally quantity present that why result show.
- **F4 (178.21±212)** it was observed that floating lag time. show lower Floating lag time because lower viscosity of **HPMC K4 M** and **karaya gum**.
- The floating lag time and total floating time of tablets of each batch are give in Table no 10.

3.4. IN-VITRO RELEASE STUDY

In vitro drug release studies were carried out using USP 25 (Type II) apparatus in 900 ml of dissolution media maintained at 37°C+0.5°C at the 50 rpm. hydrochloric acid buffer pH 1.2 was used in dissolution media. It's important to check any kind of interaction between drug candidate and polymer. The polymers which are to be incorporated into formulation should be compatible with the drug. This compatibility study or interaction study was done using Fourier transformed infrared spectroscopy.

➢ **Invitro % drug release study of all batch**

Table 6: Invitro % drug release release study of all batch.

Time (hr)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)	F7 (%)	F8 (%)	F9 (%)	F10 (%)
0	0	0	0	0	0	0	0	0	0	0
1	11.05	44.7	11.7	15	34	23.42	56.7	57.1	40	44.3
2	12.79	57.7	10	14.2	38.1	42.7	31	72.8	41.5	35.1
3	29.05	70.2	17.6	13.8	42.6	46.4	42.2	93.28	45.2	47.3
4	41.95	66.2	31.1	14.1	50.0	59.8	53	100.19	56.5	55.7
5	68.98	74.57	10.3	14.6	52.9	63.6	59	100.74	65.4	64.9
6	62.38	62.87	9.6	12.2	86	88.7	104	114.52	113.5	109.7
7	69.84	93.3	6.8	7.6	72	87	111	117.7	121	101.7
8	55.13	77.4	6.8	7.0	78.4	100.7	112	118.7	117.4	98

- In vitro release data and profile for batches F1, and f9 showed that amitriptyline Hydrochloride with HPMC K4M and Carbopol 934 gives drug release 69.84% in 7 hrs and 112% in 6 hrs. respectively.
- In vitro release data for batch F6 and F7 showed that amitriptyline with HPMC K4M and carbopol 934 gives % drug release 100% in 8 hrs and 104 % in 6 hrs.
- F6 batch is the best that slowely drug release at the standard time.
- In vitro release data for batch F2 showed that amitriptyline with HPMC K 100 and Gaur gum gives % drug release 93% in 7 hrs.
- In vitro release data for batch F3 showed that amitriptyline with HPMC K 100 and Xanthum gum gives % drug release 31% in 4 hrs.
- In vitro release data for batch F4 showed that amitriptyline with HPMC K 4 M and Karaya gum gives % drug release 14.6 % in 5 hrs.
- Both batch F3 and F4 are very fast drug release before the standard time.
- In vitro release data for batch F5 and F10 showed that amitriptyline with Xanthum gum and carbopol 934 gives % drug release 86 % in 6 hrs and 109 % in 6 hrs.
- In vitro release data for batch F8 showed that amitriptyline with HPMC K 100 and carbopol 934 gives % drug release 14.6 % in 5 hrs.

4. RESULT AND DISCUSSION

- Amitriptyline Hydrochloride is a treat chronic pain syndrome, anxiety and insomnia. It is used to treat low mood and depression. These drug were first created to treat anxity and depression. Drug is a class of medications called tricyclic antidepressants. It works by increasing the amounts of certain natural substances in the brain that are needed to maintain mental balance.
- Pre compression study are optimise batch no 6 are as evalution test as pass all parameters. The angle of repose values for formulations range from. Bulk and tapped densities were used for the measurement of compressibility index. The bulk 0.30 ± 0.12 and tapped values 0.38± 0.11. The carr's index and hausner's ratio values 10.3±6.3 and1.106±0.06.
- Drug content also give possitive responce of batch no 6. Thus all formulations exhibited good flow characteristics. All small, big parameters are passes at standard range.

ACKNOWLEDGEMENTS

A Journey is easier when you travel together. Interdependence is certainly more valuable than independence. This thesis is the result of several months of work whereby I have been

accompanied and supported by many people. It is a pleasant aspect that I have now the opportunity to express my gratitude to all of them.

Very first I respectfully acknowledge this project work to Almighty God and my parents whom I owe everything I am today.

I would like to express my deepest gratitude to **Prof.(Dr.) A. V. Chandewar Sir,** Principal: YZVS's P. Wadhwani College of Pharmacy, Yavatmal for providing much of the stimuli in the form of suggestions, guidance and support me at all stages of my work.

I would love to express my love and heartfelt gratitude to my respected mother **Mrs**. **Sonali V. Deshmukh** and my father **Mr. Vijay W. Deshmukh** for their unwavering faith and confidence on my abilities also thanks to my little sister **Dr. Maithili V. Deshmukh** to encourage me. Thank you for everything. Thanks to my grandparents **Mrs. Suman Wasudevrao Deshmukh and Mrs. Rekha Madhukarrao Babhulkar** also support me. Thank you cousin's and whole **Deshmukh family.**

I fondly thank with deepest gratitude to my honorable guide **Prof. (Dr.) S. R. Gawande** who with his deep knowledge, keen interest, of the subject, kind co-operation, untiring patience, constructive criticism, constant help and encouragement has enabled me to complete my dissertation work. Her principles, discipline, simplicity caring attitude and provision of fearless work environment will be cherished in all walks of my life.

I am deeply indebted to**, Mrs. Bakade Mam** and **Mrs. Channawar mam** Lecturers P. Wadhwani college of Pharmacy, Yavatmal for valuable guidance, never ending, support and encouragement.

I feel immense pleasure to acknowledge my profound, sincere sense of gratitude to **Ms. M. O. Khudsange** for helping me in PG and during this dissertation work. I also thank all teaching and non-teaching staff members especially for their kind co-operation and support.

I would like to thank everyone who directly or indirectly helped me in my project work. Last but not the least I pay my reverence to this institute, **P. Wadhawani College of Pharmacy,** I am undeniably proudto be associated with this college.

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