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Formulation and evaluation of *Shirish (Albizia lebbeck)* Salve for Cellulitis treatment

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Abstract

A frequent bacterial skin infection, cellulitis is a major global health concern. This study investigates the effectiveness of *Shirish (Albizia lebbeck),* which has historically been used to treat inflammation and infection. It has been demonstrated that the extract from this plant has anti-bacterial action against a variety of bacteria when applied as a salve to treat cellulitis. By conducting both in vitro and in vivo trials, the study systematically investigates and assesses *Shirish's* antibacterial and anti-inflammatory characteristics. The cream's and the extract's concentration-only antibacterial properties were correlated. The physical characteristics of all cream formulations were good; they were all smooth, emollient, non-greasy, and water-soluble. The development of *Albizia lebbeck* as a cream for *S. aureus*-caused skin infections is determined to have potential. Findings indicate promising therapeutic potential, offering a natural alternative or adjunct therapy for cellulitis management.

Key words : Salve, *Albizzia lebbeck*, Cellulitis, Erysipelas.

Cellulitis, characterized by skin inflammation and infection, predominantly caused by bacteria like Staphylococcus aureus and Streptococcus pyogenes, presents challenges in treatment due to antibiotic resistance and adverse effects. Traditional medicinal plants, such as Shirish, have long been used for their anti-inflammatory and antimicrobial properties. This aims to assess the effectiveness of Shirish salve in treating cellulitis, potentially providing a safer and more sustainable treatment option[6].

Cellulitis occurs with minor trauma or inflammation, such as cuts or cracks in the skin, and mostly enters the system through Staphylococcal bacteria commonly found in the skin, nails, and nasal membranes. Immune disorders or diabetes mellitus can cause this

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location to become the initial source of cellulitis that might spread throughout the body. Lymph nodes are vital structures in the immune system because they protect the body by filtering bacteria, viruses, and other harmful substances from the circulatory system. This function can be disrupted by cellulitis, which may cause blockage in the lymph nodes, thus allowing the bacteria to develop and cause cellulitis in the lymphatic ducts. High blood glucose can also damage both the nerves and blood vessels, slowing down blood flow, increasing the risk of neuropathy and a decrease in white blood cells during an infection[2].

Early intervention is therefore necessary for cellulitis management since it is a persistent condition that should be managed irrespective of the level of care. It affects people of all ages even those who are generally well. Certain local and general conditions predispose to it. Although acute complications are mostly rare, fortunately they can prove fatal. Long-term complications are recurrences leading to persistent lymphedema that is more likely to aggravate the condition[2].

Causes of cellulitis :

Cellulitis is an acute and painful infection that affects subcutaneous tissue and may affect deep dermal tissues or the fat layers. This infection is mostly caused by Staphylococci and Streptococci and is commonly found in adult and elderly patients. In diabetic foot infection, in particular, the risk of cellulitis is doubled if the patient has neuropathy plus ischemia. Cellulitis can appear as an isolated condition or can coexist with other necrotizing infections. Gangrene and necrosis can occur frequently and can result in amputations or death. Cellulitis can be classified into simple skin infection, complex skin infection, sepsis, and recurrent cellulitis. Because symptoms are similar, such as edema, pain, soreness, and erythema in the affected area, cellulitis is often misdiagnosed as a different condition, commonly an allergic reaction or a rash[1].

Traditional medicine often offers natural remedies for such ailments. This research investigates the potential of *Shirish (Albizia lebbeck)* in the form of a salve for treating cellulitis. The study employs a systematic approach to evaluate the efficacy of this herbal remedy through in vitro experiments. Results indicate promising antimicrobial and anti-inflammatory properties, suggesting a potential alternative or adjunct therapy for cellulitis treatment[8].

The proposed salve would combine extracts from the bark of *Shirish*. The anti-inflammatory properties and the cooling properties could potentially work together to reduce the inflammation and discomfort associated with cellulitis.

Chemicals :

Albizia lebbeck (*Shirish*) extract was acquired from AMSAR PRIVATE LIMITED , Indore , India. Soft Paraffin, Wool Fat, Cetostreyl, Hard Paraffin**.**

Apparatus : China dish, Stirrer, Measuring cylinder, Morter and Pestle, Water bath, Beaker.

Characterization of Screening of plant extract :

The extract with the most significant

inhibition zone against *S. aureus* is chosen. Then, the cream's color, smell, solubility, pH, ash value, moisture content, and extractive value are examined in detail.

Figure 1. Bark of *Albizia lebbeck*

Physicochemical properties :

They look at everything like color, smell, ability to dissolve, acidity level, ash content, water content, and extract value to understand the cream better.

Solubility profile :

We checked the solubility of *Albizia lebbeck* excerpt visually in distilled water, ethanol, methanol, and ethyl acetate by dissolving 1 mg of the medicine in a sufficient volume of each detergent**.**

Phytochemical Webbing :

Tests are performed for Carbohydrates, Alkaloids, Glycosides, Tannins, Flavonoids, Steroids, and unpredictable canvases.

Antibacterial exertion :

The nutrient agar plate is prepared and sterilized in the autoclave for 30 minutes. After removing the plate from the autoclave, bacteria are added under a laminar air flow hood. Then, 6.7 ml of solution is poured into the plates, and wells are created using a borer. Different concentrations of 1000, 1500, and 2000 µg/ml are added to the wells. The plates are then placed in an incubator for 30 minutes for incubation. Readings are taken after 24 and 48 hours of incubation.

Preformulation studies :

Identification Test - A confirmatory test for Albizia lebbeck :

FTIR study :

The pure *Albizia lebbeck* sample was analyzed using FTIR spectroscopy in the surge number range of 400-4000 cm^{-1}. The resulting printout was compared to the reference standard for analysis.

Drug excipients compatibility study :

Study on the compatibility of drug excipients: Excipients are a necessary component of almost all medicinal lozenges. Choosing the right excipients is crucial. They help make the medicine easier to take, ensure a steady release, maintain bioavailability, and prevent degradation. This selection is key to creating a stable and effective lozenge. Fourier transform infrared spectroscopy was utilized to investigate the relationship between medicine and polymers. A bullet that was translucent and thin was created by exerting pressure of 2000 psi. The bullet was exposed

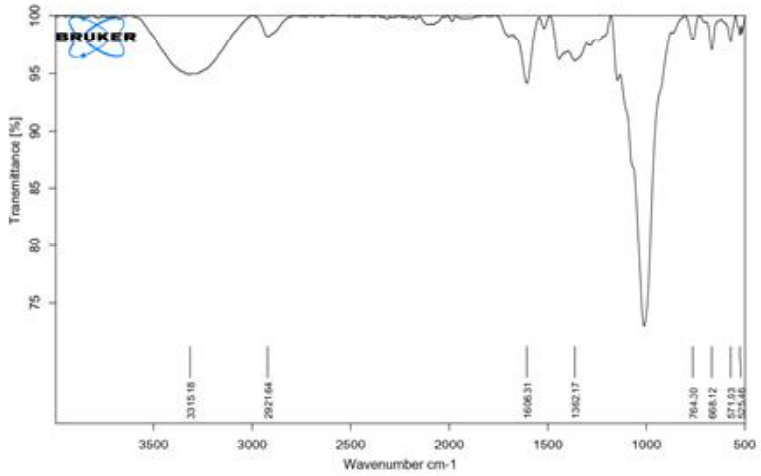

Figure 2. FTIR of Shirish

to infrared radiation, and with an FTIR spectrophotometer, readings were taken in the range of 400-4000 cm^{-1}. Screening was done using phytochemicals.

System of analysis of Albizia lebbeck :

To prepare the phosphate buffer :
you need to take 50 ml of 0.2 M KH_2PO_4 in a 200 ml volumetric beaker. Then, add a specific volume of 0.2 M NaOH and water to make the total volume up to 1000 ml.

Determination of immersion maxes (λ_{max})*:*

To make the stock solution, 10 mg of *Albizia lebbeck* was dissolved in a bit of pH 7.4 phosphate buffer. The volume was then increased to 100 ml with the same buffer to reach a concentration of 100 µg/ml. The stock solution was combined with additional pH 7.4 phosphate buffer and tested in the UV range using a Shimadzu UV spectrophotometer.

Standard estimation wind of Albizia lebbeck in Buffer :

The stock solution was created by mixing 10 mg of *Albizia lebbeck* in a bit of pH 7.4 phosphate buffer and then adjusting the volume to 100 ml with the same buffer to get a concentration of 100 µg/ml. Portions of 10, 30, 50, 70, and 90 ml were taken from this stock solution and poured into separate 10 ml volumetric beakers. Each portion was diluted with phosphate buffer to achieve concentrations of 10, 30, 50, 70, and 90 µg/ml. The absorbance of these solutions was measured at a wavelength of 252 nm using a UV spectrophotometer against 0.1 N HCl.

Evaluation studies of preparation :
Anti Cellulitis exertion :

Agar well prolixity system checked the exertion. Excerpt ran been checked for the exertion of the zone of inhibition. The nutrient agar plate was prepared and autoclaved for

30 minutes for sterilization. After removing it from the autoclave, the plate was placed under laminar airflow. Following that, bacteria were added to the plates, and then the plates were left to solidify. The paragraph also includes this made borer wells 1000,1500,2000 µg/ ml is taken and included into the wells (incubation of plate for 30min same like…) the except attention and above-made dish holders to incubator Reading other for 24 and 48 hrs.

pH :

After properly adjusted, the pH from the expression was determined employing a pH cadence. After that, the instrument was adjusted using buffer solutions with pH 4 and pH 7 by dialing the electrode into them. The pH of the ointment was then recorded. Data was collected in triplet; means were calculated and SD is shown.

Acid value :

Acid Value of substance dissolved in 50 ml admixture of alcohol and solvent ether; the beaker directly counted with 10 gms. The beaker is linked through influx condenser slackly hotted until sample is dissolved fully titrated sluggishly with N NaOH when taint pink shade appears after littering for almost half a minute then add to this 1 ml with phenolphthalein.

To calculate the acid value, you need to multiply the number of milliliters of NaOH needed by 5.61 and then divide that by the weight of the substance.

Saponification value :

To find the saponification value, subtract the initial volume of titrant (a) from the final volume of titrant (b), then multiply the result by 28.05, and finally divide by the weight of the substance in grams (w).

Spreadability :

To calculate the spreadibility, you multiply the weight tied to the upper slide by the length of the glass slide and then divide by the time taken to fully separate the slides from each other.

Viscosity :

The viscosity of the ointment was determined using a Brookfield Rheometer viscometer with spindle number 96 at 10 RPM and a temperature of 30 ± 2 ^{o}C. The density of the ointment was determined, and the results were recorded in triplicate to calculate the standard deviation. In the in-vitro saturation study, the cream's medication content was assessed using a UV-visible spectroscopic system. Samples of the cream were mixed with Phosphate buffer and analyzed at a wavelength of 252 nm using a UV-VIS spectroscopic system. The findings were noted three times, and then the standard deviation was computed.

FTIR study :

The FTIR spectrum of pure Albizia lebbeck showed specific peaks at 2951, 1306, and 1265 cm^{-1}, which suggest the presence of -CH stretching linked to the -C=N and C-S bonds. Moreover, distinct peaks at 1564 and 1458 cm^{-1} were seen, indicating the stretching vibration of -C=C bonds.

FTIR illustration :

The pure *Albizia lebbeck* and its mixture with Stearyl Alcohol were separately

mixed with IR grade KBr and analyzed across a range of 400-4500 cm^{-1} using an FTIR instrument. It was observed that there were no significant peak changes in the FTIR spectrum of *Albizia lebbeck*. The FTIR spectra of the medicine-polymer mixture and the physical combination of all components used in tablet formulation were also examined. The FTIR analysis indicated no physical or chemical interactions between Stearyl alcohol, white beeswax, or any other excipients.

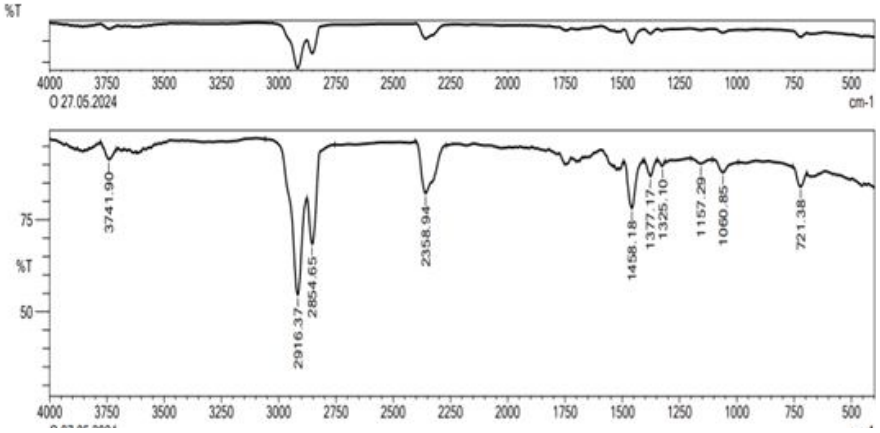

Figure 3. FTIR Spectra of Formulation

Physicochemical properties:

They examined all the characteristics such as color, smell, solubility, pH, ash value, moisture content, and extractive value.

Table-1. Organoleptic Properties of *Albizia lebbeck*

Color	Brown
Odour	Characteristics odour
Taste	Astringent Taste

Table-2. Solubility Profile

Sr No.	Solvent	Solubility
1	Distilled water	Completely soluble
2	Ethanol	Insoluble
3	Methanol	Insoluble
4	Ethyl Acetate	Insoluble
5	Dimethyl Peroxide	Insoluble

Table-3. Physicochemical properties

Parameter	% Value
Loss on drying	11.3
Total ash	18.2
Acid solution ash	11.4
Water soluble ash	1.84
Ethyl acetate soluble extractive value	2.4
Petroleum ether soluble extractive value	0.8
Aqueous soluble extractive value	21.6
Acetone soluble extractive value	7.3

Phytochemical screening :

Test for carbohydrates, alkaloids, glycosides, tannins, flavonoids, steroids, volatile oils.

Table-4. Phytochemical Screening

Chemical Test	Test Results
Alkaloids	-
Flavonoids	+
Tannins	+
Cardiac Glycosides	-
Triterpenes	+
Steroids	-
Saponins	-

Table-5. Factorial for formulation of cream

Formulation Code	Shirish (mg)	Hard Paraffin	Wool Fat	Cetostreyl Alcohol	Soft Paraffin
0F1	60	1	5	5	8.5
0F2	60	5.8	3	5	8.5
0F3	60	3	0.1	5	8.5
0F4	60	5	5	5	8.5
0F5	60	1	3	5	8.5
0F6	60	3	3	5	8.5
0F7	60	3	5.8	5	8.5
0F8	60	5	1	5	8.5
0F9	60	0.1	3	5	8.5

Table-6 Post-compression parameters of preliminary batches

Batch Code	Ph	Spreadability (gm.cm/sec)	Viscosity(cps) (100rpm)
0F1	6.7	13.33	1423
0F2	6.7	14.55	1523
0F3	6.8	15.65	1679
0F4	6.7	16.52	1779
0F5	6.8	16.45	1813
0F6	6.7	17.78	1984
0F7	6.8	17	2003
0F8	6.8	16.45	1874
0F9	6.7	18.45	1895

Preaparation of ointment :

Procedure for medication of Ointment:

First, the hard paraffin was directly counted and grated. It was also melted in a sinking dish on a water bath. After the hard paraffin melted, the other constituents were added and gently stirred to help them melt and mix unevenly. Eventually, the ointment base was allowed to cool down[4].

The herbal ointment was made by mixing directly counted Neem and Turmeric except with the ointment base using the levigation system. This was done to produce a smooth paste with two or three times its weight of the base. further base was gradationally added until a homogeneous ointment was formed, which was also transferred into a suitable vessel[6].

Figure 4. Prepared *Albizia lebbeck* Herbal ointment

Figure 5. Prepared *Albizia lebbeck* Herbal ointment

Post-compression evaluation of primary trial batches :

The evaluation of the batches involved measuring the density, pH, zone of inhibition, and spreadibility of the cream for the first 9 batches of the medication.

Here are the Figure plots and Response surface plots :

The graphs display how X1 and X2 are related at specific points of 1,0 and 1, illustrating the noise figure. These plots in two dimensions help clarify how independent and dependent variables are connected.

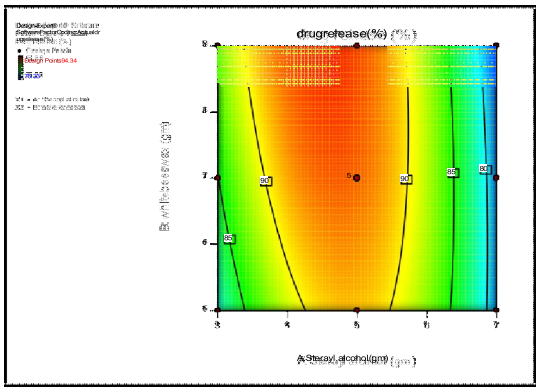

Figure 6. The contour plot illustrates how the quantity of Cetyl alcohol (X1) and Hard Paraffin wax (X2) impact the response Y3.

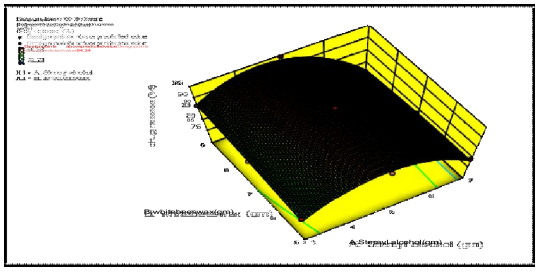

Figure 7. The response surface plot displays how the amount of Cetyl alcohol (X1) and Soft Paraffin wax (X2) influence the response Y3.

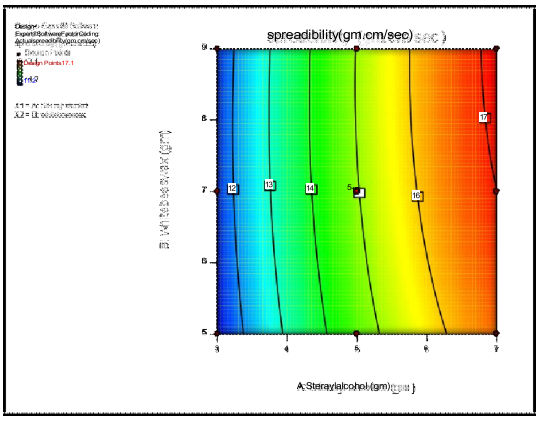

Figure 8. The contour plot shows how the amount of Cetosteryl alcohol (X1) and Soft Paraffin wax (X2) impact the response Y1.

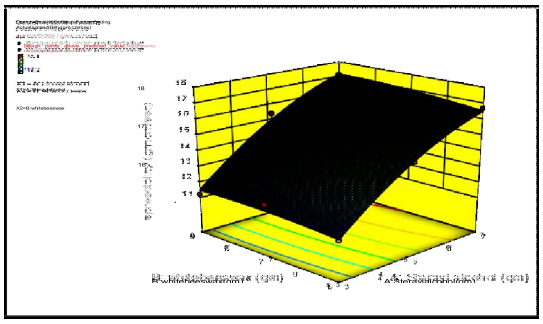

Figure 9. The response surface plot demonstrates how the quantity of Cetostryl alcohol (X1) and hard Paraffin wax (X2) influence the response Y1.

Optimized formula selection :

Once equation store late the dependent and independent variables for the reduced model polynomial, it was possible to optimize these for all three of the responses. Selected an optimal formulation based upon the constraints established on independent variables. All these extensive grid search and feasibility search calculations gave the final optimal experimental parameters. Final modeling software provides feasibility search based exhaustive grid-search.

Table-7. Formulation of Drug release data of optimized batches

Time (min)	Absor-bance	Conc. (mcg/ml)	Conc. (mg/ml)	Conc. *DF	%drug release
0	0.000	0	0	0	0
15	0.200	69.3	0.086	0.076	12.79
30	0.476	153.3	0.198	0.165	26.85
60	0.798	251.3	0.265	0.340	45.65
90	0.890	307.6	0.378	0.377	54.65
120	0.089	35.0	0.067	0.043	64.44
150	0.164	44.36	0.054	0.051	77.35
180	0.139	46.25	0.064	0.053	88.23

The drug release was planned to be 81.23% over a duration of 180 minutes.

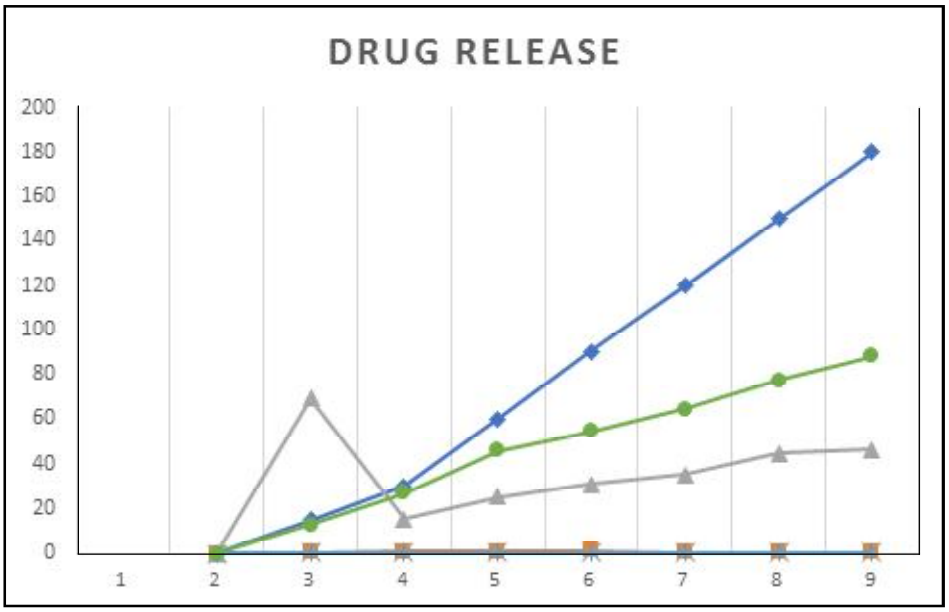

Figure 10: % Drug Release

Table-8. Evaluation of optimized batch after stability study

Samplig Interval days	Storage condition at40°C ± 2°C/75 ± 5% RH			
	Physical Appearance	pH±SD	Viscosity±SD	Spreadability ± SD
0	Light	6.02±0.0	1866.67±57	17.22±1.
	Brown	35	.73	65
15	N	6.01±0.0	1866.67±57	17.18±1.
	Change	3	.73	92
30	No	6.01±0.0	1833.33±57	17.17±1.
	Change	2	.75	93

Homogeneity :

The figure plots show the relationship between X1 and X2 at fixed positions of 1,0 and 1, visually representing the noise figure. These two-dimensional plots help explain the relationship between independent and dependent variables. Response face plots are indeed useful in understanding both the main and interaction effects of the independent variables.

Consistency :

The test for consistency provides important information about the firmness and consistency of the cream. This is crucial for ensuring that the cream remains stable over a long period and maintains its uniformity without any changes.

Observed value :

The consistency of the formulation is measured at 5.2 mm. The saponification value is noted to be 187, and the acid value is observed to be 0.62**.**

The research found that the ointment containing *Albizia lebbeck* extract has effective antibacterial properties, suitable for treating Cellulitis disease. Selected plant extracts were incorporated into the cream after confirming the purity of the drug and individual excipients. The ointment formulation followed an o/w preparation method. The physicochemical properties and phytoconstituents of *Albizia lebbeck* extract were analyzed first to ensure extract purity.

The pH, viscosity, and Spreadability were assessed. Factorial designs were used to optimize the final formulation with minimal trials. The results showed that white beeswax could increase viscosity, Spreadability, and the percentage of drug release. The stability tests of the best formulation showed that there were no big changes in how it looked, its pH, how well it spreads, and its thickness over a month (40ºC/75% RH). The goal of creating the herbal ointment was successfully met. Skin irritation was observed, which may require further investigation.

Future scope :

1. Clinical trials to evaluate the safety and efficacy of *Shirish* salve in human subjects with cellulitis.

2. Optimization of salve formulation to enhance stability and bioavailability of active compounds.

3. Investigation of potential synergistic effects of *Shirish* with other herbal ingredients or conventional antibiotics.

4. Elucidation of the underlying molecular mechanisms of action through advanced pharmacological studies.

5. Development of standardized protocols for manufacturing and quality control of Shirish salve to ensure consistency and reproducibility.

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