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Research Article

**FORMULATION DEVELOPMENT AND EVALUATION OF
MEDICATED JELLY WITH CUMINUM CYMINUM EXTRACT
AND ITS COMPARATIVE STUDY USING DIFFERENT
JELLING AGENTS****Prabhat Dessai*and Kajal Rao**Post Graduate Department of Chemistry, Dyanprassarak Mandal's College and Research Centre
Assagao- Goa 403507-India**Abstract:**

Convenience of administration and patient compliance are gaining significant importance in the design of dosage forms. Present study was aimed to formulate and evaluate medicated Jelly of Cuminum cyminum using polymers like sodium alginate and tragacanth. Difficulty in swallowing is common among all age groups, especially in elderly and pediatrics. Physical characteristics, pH, in vitro % drug release kinetics, content uniformity, spreadability, IR spectral analysis, and stability studies were conducted. IR spectroscopic studies indicated that there were no drug-excipient interactions with tragacanth but was an interection with sodium alginate. The prepared jellies of Cuminum cyminum were found to be stable and there are no significant changes in physical appearance, pH, In vitro dissolution studies. Thus, the study confirmed that the Cuminum cyminum oral jelly can be used as a possible alternative to recently available oral formulations.

Keywords: *Cuminum cyminum, sodium alginate, tragacanth.***Corresponding author:****Prabhat Dessai,**Post Graduate Department of Chemistry,
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INTRODUCTION:

Recently, plant extracts have again become important as an environmentally acceptable, readily available, and renewable source for a wide range of needed inhibitors. Plant extracts are viewed as an incredibly rich source of naturally synthesized chemical compounds that can be extracted by simple procedures with low cost. Jellies are transparent, opaque, non-greasy semisolid gels generally applied externally. They are used for medication, lubrication and some miscellaneous application. Gelling agent used normally are tragacanth, sodium alginate, pectin, starch, gelatin, cellulose derivative like HPMC, SCMC, MC, carbomer. Preparations containing gelling agent that merges or entangles to form a three-dimensional colloidal network structure. Medicated jellies are chiefly used on mucus membrane and skin for their spermicidal, local anesthetic and antiseptic properties. Skin injuries, local infections and tissue cleansing can be best treated by application of product that form transparent water vapour and air permeable film over the skin surface from which the drug releases continuously from the application site. Cuminum cyminum is an annular herbaceous plant belonging to the family Apiaceae. It has an agreeable taste and an aromatic odour. Its seeds are used to prepare decoction, which is sometimes used in treating flatulence and indigestion. Cumin seeds contain numerous phyto-chemicals that are known to have anti-oxidant, carminative and anti-flatulent properties. Therefore, the present study was carried out to formulate a medicated jelly with Cuminum cyminum extract by using different gelling agents like sodium alginate and tragacanth in various proportions.

MATERIALS AND METHODS:

Plant material:

Cuminum cyminum was collected from the central stores of Goa

Chemicals:

Sodium alginate and Tragacanth were purchased from

Methods:

Preparation of Cuminum cyminum extract:

Cuminum cyminum was boiled with water for period of 15 minutes. Then the liquid extract was collected.

Formulation of Jellies:

All the formulations were prepared using freshly boiled and cooled distilled water as per the composition listed in Table 1. Cuminum cyminum extract was mixed with alcohol and glycerin with small quantity of water prior to the addition of the jelling agents. Mucilage's were prepared with jelling

agents sodium alginate & tragacanth. The extract mixture was added to the mucilage's & shaken well in order to get medicated jelly.

Evaluation of formulated jellies:

Prepared Cumin extract jellies were evaluated for appearance, pH, spreadability, stability. All the formulations were visually inspected for clarity, colour.

Appearance:

The Cumin extract jellies having sodium alginate was creamish in appearance whereas with tragacanth it was brown in appearance.

Stickiness and grittiness:

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.

Determination of pH:

The pH values (Table 2) of 1% aqueous solutions of the prepared jellies were checked by using a calibrated digital pH meter at constant temperature. For this purpose 0.5g of jelly was dispersed in 50ml of distilled water to make 1% solution and pH was noted.

Spreadability:

For the determination of spreadability excess of sample was applied in between two glass slides and was compressed to uniform thickness by placing 1000 gm weight for 5 minutes. The time required to separate the two slides i.e., the time in which upper glass slide moves over the lower plate was taken as measure of spreadability.

$$S = m \times l / t$$

Where; m=weight tide to upper slide,

l=length moved on glass slide,

t=time taken.

Content uniformity:

1 medicated jelly from each formulation taken and dissolves in 50ml of phosphate buffer pH 6.8 to give 100g/ml solution. From the above solution 1, 1.5, 2ml is taken and made up to 10ml with pH 6.8 phosphate buffer to give 10, 15, 20ml g/ml solutions respectively. The absorbance of each solution was measured at 232nm using UV-Visible Spectrophotometry.

Moisture content

The prepared films are weighed individually and kept in a dessicator containing calcium chloride at room temperature for 24hrs. The films are weighed again after a specified interval until they show a constant

weight. The percent moisture content is calculated using following formula.

$$\% \text{moisture content} = \frac{\text{initial weight} - \text{final weight}}{\text{initial weight}} \times 100$$

Stability studies:

All formulation prepared were kept for 3 months under room temperature, higher temperature and lower temperature for its stability and for further studies. Data was given in table-2.

Syneresis:

Syneresis is the contraction of the gel upon storage and separation of water from the gel. It is more pronounced in the gels, where lower concentration of gelling agent is employed. All the jellies were observed for signs of syneresis at room temp ($25^{\circ}\text{C} \pm 5^{\circ}\text{C}$). The formulations showing signs of syneresis were rejected and not considered for further studies.

Drug-Excipient Compatibility Studies

The drug and excipients were mixed together in 1:1 ratio and placed in borosilicate colored glass vials. These vials were sealed and placed in an oven maintained at 40°C and 75% RH. The samples were observed after 15, 30 and 45 days for any color change or lump formation. Fourier transforms infrared (FTIR) spectra of the pure drug and its mixtures of gelling agents were measured by preparing dispersion in dry KBr using attenuated total reflectance FTIR spectrophotometer. The absorption maxima in the spectra obtained were compared, and the presence of additional peaks corresponding to the functional groups was noted.

In vitro Dissolution Studies:

In-vitro drug release study of jellies was carried out by using the paddle apparatus method. The dissolution test was carried out using 900 ml of phosphate buffer pH 6.8 solution at 37°C and 75 RPM. A sample (5 ml) of the solution was withdrawn from the dissolution apparatus at 10, 20, 30, 40, 50, and 60 min and withdrawn volume was replaced with fresh dissolution media.

Following parameters were used for the dissolution study.

1. Apparatus: USP dissolution apparatus type II (paddle type)
2. Speed of the paddle: 75 RPM
3. Temperature: 37.5°C
4. Dissolution medium: Phosphate buffer pH 6.8
5. Volume of medium: 900 ml
6. Sampling time: 10, 20, 30, 40, 50 and 60 minutes

Anti bacterial activity

Anti bacterial activity of the ideal formulated jelly was conducted by standard agar disc diffusion method. Muller Hinton agar medium was prepared and sterilised as per standard procedure. Inoculation of the selected bacterial culture was done by spread plate technique. After 10 min hole of about 4-5 mm in dm were bored in the medium with sterile borer and filled by test formulation a standard containing gentamycin (10mcg) disc and a control to plate containing jelly Cumin extract was also prepared. After 18-24 hours of incubation at 37°C , the diameter of one of inhibition around each hole was measured.

RESULT AND DISCUSSION:

Based on the physicochemical

Physical observation

Physical observation of jellies is important to justify the patient acceptance and compliance of the products. The observed parameters are summarized in Table 2. of all the formulations F2 showed best results being sticky with an acceptable consistency. Spreadability is the parameter which will help in the uniform application of gels to the skin. A good gels takes less time to spread and will have high spreadability.

Stability studies

The samples were characterized for change in various parameters such as appearance, pH, syneresis and drug content at the end of 90 days. A freshly made sample was used as a reference standard for subjective evaluations. (Table 4)

Table 1: Formulations

INGREDIENTS	F1	F2	F3	F4
Jelling agent	20%	30%	40%	50%
Herbal medicine	25%	25%	25%	25%
Alcohol	10%	10%	10%	10%
Glycerin	15%	15%	15%	15%
Water	Qs	qs	qs	qs
Preservative	0.01	0.01	0.01	0.01

Table 2: Physicochemical parameters of Cuminum cyminum jellies

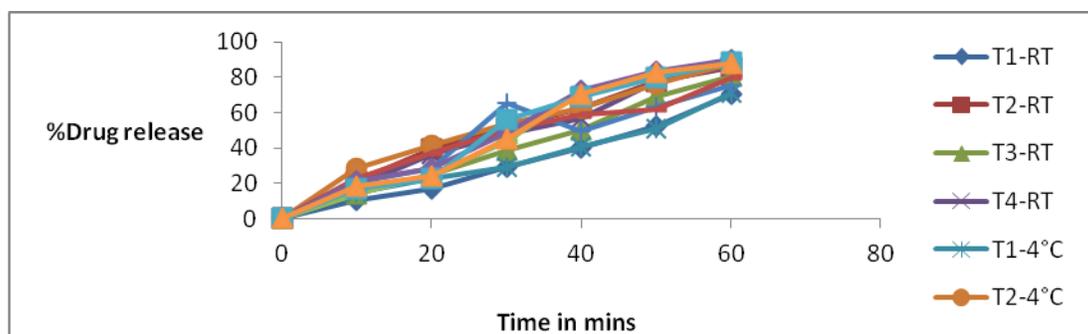
Formulations	Appearance	Texture	Texture	Syneresis
F1	Cloudy	Sticky	Sticky	-
F2	Cloudy	Sticky	Sticky	-
F3	Cloudy	Slightly sticky	Slightly sticky	-
F4	Cloudy	Slightly sticky	Slightly sticky	-
F5	Cloudy	Sticky	Sticky	-
F6	Cloudy	Slightly sticky	Slightly sticky	-
F7	Cloudy	Non sticky	Non sticky	-
F8	Cloudy	Non sticky	Non sticky	-

Table 3: Drug Contents

Formulations	Drug content	Moisture content	pH of the jelly
F1	98.46	21	4.25
F2	99.36	19	3.95
F3	101.13	19	3.98
F4	100.35	9	3.80
F5	101.32	20	5.25
F6	97.65	18	5.00
F7	96.15	17	4.92
F8	102.30	7	4.80

Table 4: Dissolution studies

Time in mins	Tragacanth				Sodium alginate			
	T1	T2	T3	T4	S1	S2	S3	S4
0	0	0	0	0	0	0	0	0
10	9.5	39.2	16.2	26.3	15.3	13.7	12.5	10.9
20	14.8	42.8	18.9	29.1	20.4	16.5	15.2	14.6
30	25.5	56.1	36.5	42.8	32.6	28.4	27.1	26.5
40	30.6	68.4	50.1	57.0	41.0	32.9	30.5	35.9
50	42.9	85.9	68.5	79.2	54.9	44.6	42.9	49.2
60	80.4	94.2	79.6	89.4	75.9	51.4	50.9	52.6

**Fig. 1: Stability studies of 1 month with Tragacanth**

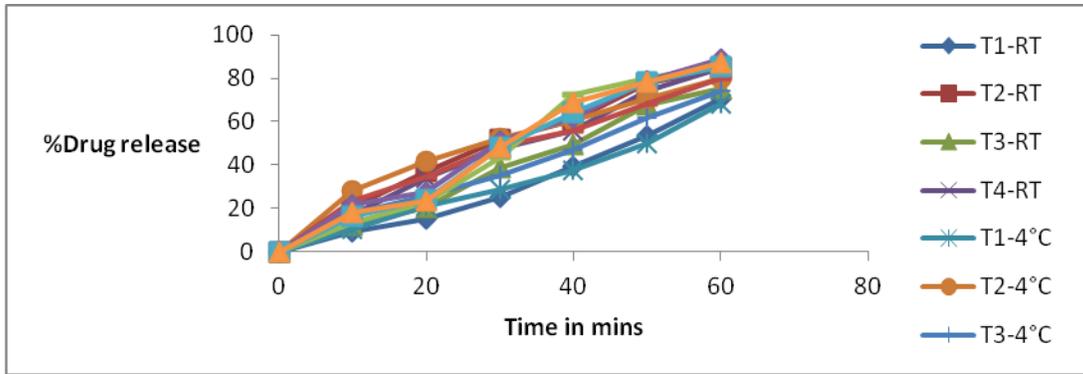


Fig. 2: Stability studies of 2 months with Tragacanth

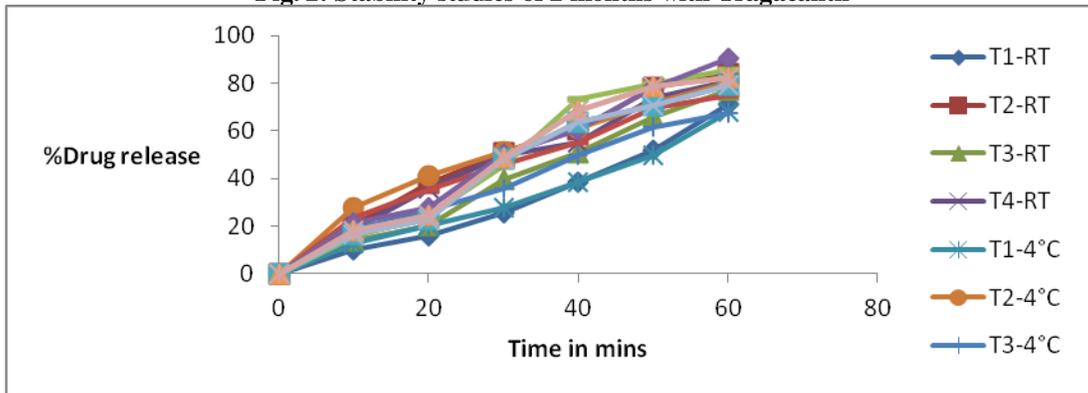


Fig. 3: Stability studies of 3 months with Tragacanth

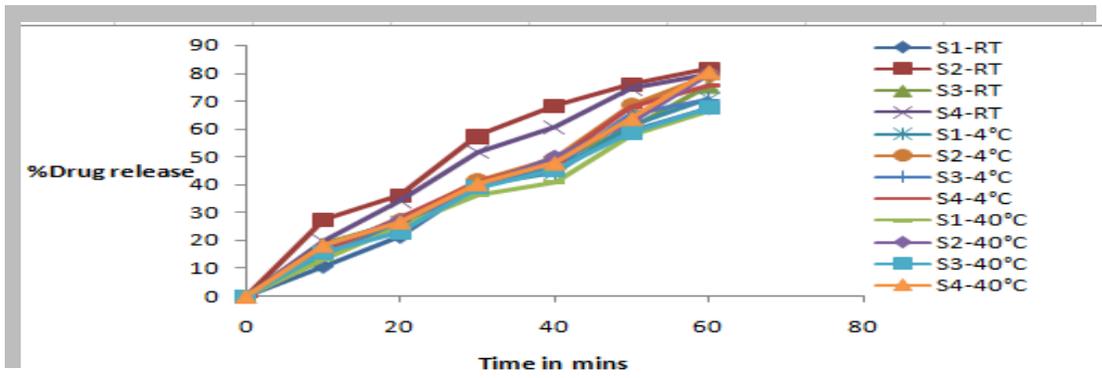


Fig. 4: Stability studies of 1 month with Sodium Alginate

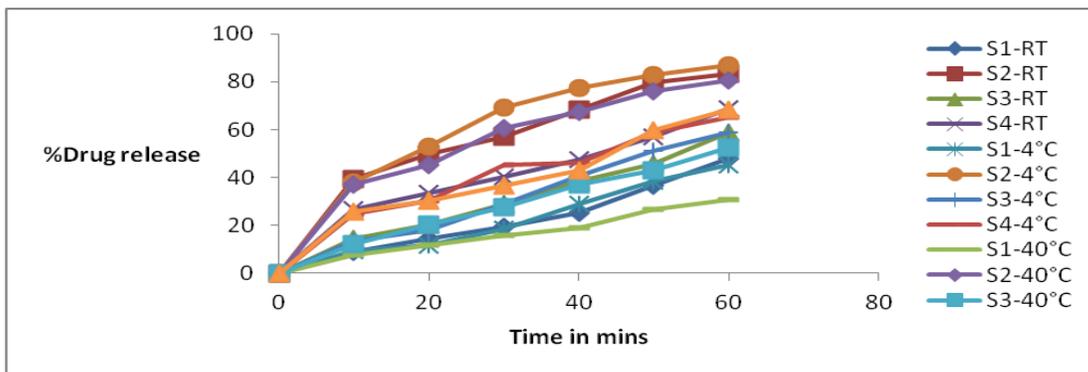


Fig. 5: Stability studies of 2 months with Sodium Alginate

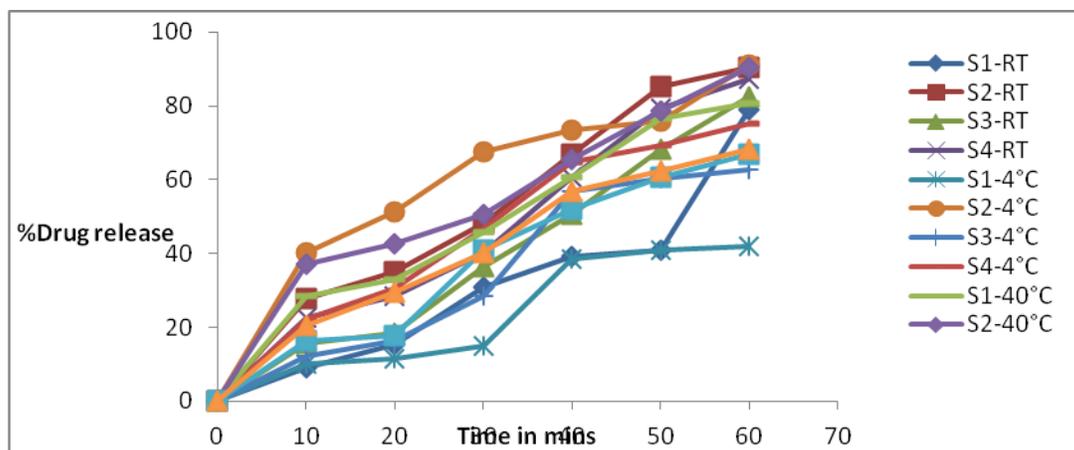


Fig 6: Stability studies of 3 months with Sodium Alginate

Table 5: Anti bacterial activity

Formulation code	Zone of inhibition in mm
F1	7mm
F2	10mm

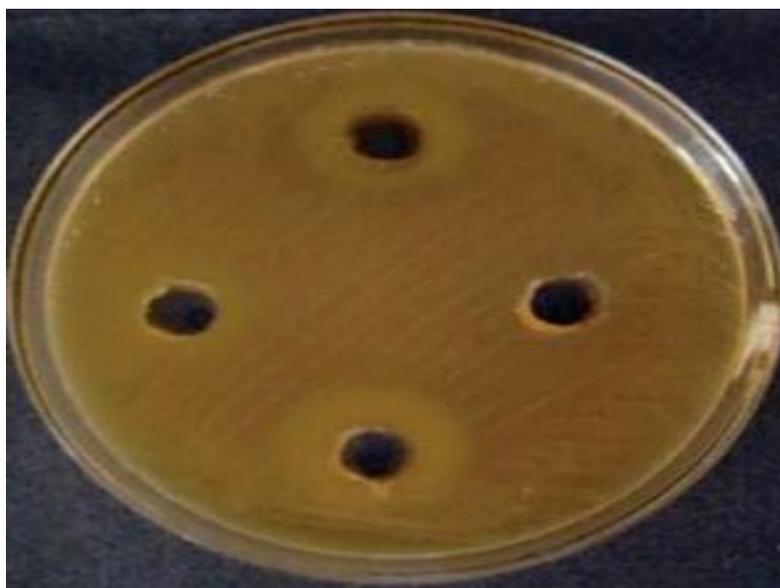


Fig. 7: Zone of inhibition

CONCLUSION:

Medicated jelly with Cuminum cyminum extract was formulated using tragacanth. Jelly with tragacanth shows good physicochemical properties. These will have additional advantages of patient compliance, convenience and comfortness for efficient treatment including low dose, immediate onset of action, reduced dosage regimen and economic. The Physico-chemical characterization revealed that all the formulations were found to show acceptable pH, spreadability and syneresis. The drug content

estimation showed uniform drug content in all the formulations. IR spectroscopic studies indicated that there were no drug-excipients interactions. The stability studies proved that the prepared Medicated jellies were found to be stable when stored in air tight containers. Hence the present piece of investigation will be used for industry, research and development division. Hence, the formulations prepared were compatible to use as drug delivery. However preclinical studies of this formulation need to be done.

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