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FORMULATION AND EVALUATION OF MUCOADHESIVE GEL OF Moringa oleifera AND Myrica nagi FOR NASAL DRUG DELIVERY SYSTEM.

Dr Richa Srivastava[1], Dr. Anuradha Singh[2]

[1]Professor Kashi Institute of Pharmacy Varanasi-Prayagraj Road Mirzamurad Varanasi 221307-UP, lilllyricha@gmail.com
[2]SBS group of educational and training institutes. University name with city, Pincode : SBS group of educational and training institutes. Malwan. Fatehpur (UP) 212664, thisismeanuradha18@gmail.com
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KEYWORDS

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Abstract

The current study comprises the natural formulation and evaluation of the poly herbal mucoadhesive gel using extracts of Moringa olifera and Myrica nagi, which is endowed with effective potential for treating rhinitis. Previous research works reported that polymers were originated to effectively blend with the herbal products.Thus it forms mucoadhesive gels with effective drug release. Evaluation and description of poly herbal mucoadhesive gel formulation of Moringa oleifera and Myrica nagi were used for nasal drug delivery. Results are obtained by evaluating herbal mucoadhesive polymers gel and studies are performed by comparing the poly herbal extracts: Myrica nagi and Moringa oleifera. Since the nasal mucoadhesive gel involves drug release based on diffusion over a prolonged/controlled time interval;Viscosity, temperature of gelling and spreadability factors influences the drug release. By utilizing RSM methodology by Box-Behnken the optimization of situ nasal gel formulation was carried out. From determining the effective formulation of gel were further objected to situ drug release. From the following statistical investigation, we have concluded that they possess substantial viscosity and good mucoadhesive property. It can be finalized that in situ poly herbal mucoadhesive gels act as an effective and evolutional for nasal drug delivery systems in a herbal way.

INTRODUCTION

Inearlier decade the pharmacologicalindustriesreveals a great interest in developing improved ways of drug delivery. Even though there are numerous various routes of administering a drug, the nasal cavity usage in delivery of drug has triggered a lot of researchers in developing a novel method. Due to the uniqueness in the physiological features of this nasal cavity many researchers find it as an effective way in implementing widearray of drugs (Anand et al., 2012).

Most of the leading advantages in using the route of nasal are as follows: For the direct spreadableexistence into the appropriate system will be circulatedby the drug, delivery of transnasal drug is effective than other. Due to the occurrence of innumerable amounts of microvilli in the sub-epithelial region of nasal mucosa appears to be highly vascularized;it assists in absorption of the drugs quite rapidly. It is to be on par with the I.V. administration in most of the cases. This way of administration is patient friendly, non-invasive and can be smear painlessly (Chaturvedi, 2011).

By devising an effective waydelivery of nasal drug which concentrate mainly on increasing the

interaction time.The low formulation's viscosnature leads to improper dosage due to previous nasal drip. However this can be eluded by using nasal gels as a substitute for drug delivery. Their high viscosity nature could act as an effective way for responding problems related to previous nasal drip (Ibrahim A. Alsarra et al., 2009). Mucoadhesive gels for delivery of nasal drug have created a new platform in the recent years. Unlike the typical formulation patterns such as insufflations, nasal sprays and nasal solutions, the mucoadhesive agents have a better range of contact (Basu and Bandyopadhyay, 2011).

The usages of plant as drugs are practiced from the primitive times which could be earlier to the substance of the human race. Utilizing variouschunks of the plants or the whole plant as a medicine for treating different diseases has been followed by the humans traditionally till this date. Meanwhile, the availability of plants in abundance, researchers and scientists are attempting to discover the novel methods in developingsystem of drug delivery using plants (Kulkarni, 2017). *Myrica nagi i*s one of the family belonged to the *Myricaceae*. The bark is acknowledged for its therapeutic value. The compound myricitin has bactericidal nature. *Moringa oleifera* is one of the family belonged to the *Moringaceae*. Its therapeutic usage is broadly known for treating chronic hyperglycemia, dyslipidemia and acts as an effective prophylactic agent (Jed W. Fahey, 2005).

Few of the naturally derived compounds such as chitosan, starch, guar gum, carrageenan, cellulose, pectin, xanthan gum etc., areused as a formulating agent todeliver drug and for prolonged/controlled spread of the drugs to the designated system. Few of the widely used ROA using biodegradable products are: nasal, oral, ocular, transdermal as they are effective and comparatively easy (Yadav et al., 2013). In the instant investigation of preparing mucoadhesive gel using both the synthetic polymers and natural polymers like chitosan, peg4000, gellan gum, pluronic F127 and xanthan gum using the extracts derived from the *Moringa oleifera* and the *Myrica nagi*.

Materials and methods

*Myrica nagi*and *Moringa olifera* procured from the local market and they were authenticated by State Ayurvedic College Lucknow with specimen number 1 and 3 respectively Pluronic F127, chitosan, PEG 4000, xanthan gum and gellan gum were provided by SDFCL ltd. Double time distillated water was used in all part of the studies. The Analytical grade reagents and chemicals are used in this study.

Preparation of plant extract

The fresh leaves are accumulated from *Myrica nagi*and *Moringa olifera* were shade dried. The dried plant leaves arepowdered pity coarsely and enclosed in acontainer which was air-tightened. Equal part of the two plants were mixed together and (100 g) of the herbal formulation (coarse power) was then subjected to aqueous phase extraction using percolation method. The collected extractor was vacuum dried until its use.

Formulation of nasal hydro gel:

For preparing nasal hydrogel formulation, initially the polymers such as pluronic F127, chitosan, peg400,xanthangum and gellan gum were taken and immersed in the distilled water which containspropyl

paraben andmethyl paraben along with glycerine over night. The plant extracts of *Myrica nagi*and *Moringa olifera* was then taken and was added to the polymer dispersion which was then objected to constant stirring for 10 minutes. Here few of the parameters should be considered such as pH, spreadability, temperature of gelling and viscosity of it was evaluated for each formulation to get the designated result.

Selection of an optimized nasal mucoadhesive gel formulation using response surface methodology

A 3-factor 3-level Box-Behnken statistical Design Expert software (Version 10.0.7, Stat-Ease Inc., Minneapolis, MN) was applied to control the quadratic response surface and develop a second-order equation for mucoadhesive gel optimization (Box and Behnken, 1960). The variables are independentand those variables are shown in Table 1 along with minimum, medium and maximum ranges. Evaluation on statistical grounds of main interaction of quadratic effects is taken into accounts for the variables which are independent such as viscosity, gelling time and spreadability. Design matrix composed of 17 experiments to run which was developed. The nonlinear equation of the quadratic model is:

$$Y = b_0 + b_1 X_1 + b_2 X_2 + b_3 X_3 + b_{12} X_1 X_2 + b_{13} X_1 X_3 + b_{23} X_2 X_3 + b_{23} X_2 X_3 + b_{11} X_1^2 + b_{22} X_2^2 + b_{33} X_3^2$$

Y represents the overall response with each level of factors and their combinations; b_0 is the intercept; the regression coefficients are represented from b_1-b_{33}. The concentration of herbal extracts of Moringa olifera (w/w %) (X_1), Myrica Nagi (w/w %) (X_2) and polymer (X_3) are considered as independent variables and Viscosity, spreadability and Gelling temperature are considered as dependent variables and their responses are determined in Table 2.

Table 1. Variables in Box-Behnken design

Factor	Levels Used		
	Low (-1)	Medium (0)	High (+1)
Independent variables	2	3	4
X1= *Myrica nagi* concentration (%w/w)			
X2= *Moringa olifera* concentration (%w/w)	2	3	4
X3= *Polymer* concentration (%w/w)	10	15	20
Dependent variable			
Y1= Viscosity (CP)	4000≤Y1≤7000		
Y2= Spreadability (g.cm/s)	6≤Y2≤11		
Y3= Gelling temperature (°C)	32 ≤ Y3 ≤ 37		

Table 1. Box-Behnken design for observed responses in optimization of nasal gel formulation

Batch run	Independent variables			Dependent variables			pH	Gelling time (s)
	X1	X2	X3	Y1	Y2	Y3		
1	2	4	15	6875	5.98	32.6	4.58	10
2	3	3	15	7456	7.65	33.86	5.01	11
3	3	3	15	7258	7.54	33.78	5.01	11
4	3	3	15	7158	7.12	33.82	5.01	12
5	4	2	15	8969	7.23	34.78	4.78	9
6	2	3	10	6158	3.21	32.15	4.61	13
7	3	4	20	9876	10.68	35.16	5.4	7
8	4	3	10	7120	3.89	35.86	5.56	10
9	4	3	20	9251	12.56	36.12	5.56	8
10	3	2	10	4876	4.51	33.25	4.67	14
11	3	3	15	6251	7.98	32.6	5.01	12
12	2	3	20	5876	11.21	32.86	4.77	9
13	3	3	15	5456	8.12	35.12	5.05	12
14	2	2	15	7285	7.12	32.76	4.25	13
15	3	4	10	6185	9.68	35.98	5.81	14
16	3	2	20	6250	14.23	32.54	5.32	8
17	4	4	15	12560	8.96	36.18	5.89	9

Table. 2. Composition of the optimized drug formulations subjected for in vitro drug release

Ingredient (% w/w)	F1	F2	F3	F4
Pluronic F-127	7	9	10	14
Chitosan	0.5	0.5	0.5	0.5
Herbal formulation	1	1	2	2
Xanthan gum	0.1	0.1	0.2	0.2
Gellan gum	0.2	0.4	0.6	0.8
PEG 400	10	10	10	10
Methyl paraben	0.15	0.15	0.15	0.15
Propyl paraben	0.05	0.05	0.05	0.05
Glycerine	6	6	6	6
Water	qs	qs	qs	qs

pH

Various formulations of pH werevaried by using the digital pH meter. An accurately weighed 2.5 g of gel is dissolved in distilled water of 25 ml. The content will be stored for two hours as a temporary storage. Each formulation of pH will measure in triplicates (Nisha et al., 2012).

Spreadability

The gel's spreadability was denoted,the gel spread in a glass plate in the range of 0.5 g over 2 cm of pre-marked diameter and then in 2nd glass plate wereengaged. In the period of 5 minutes a half kilogram weight was permitted to the glass plate in upper was applied. After applying gel the diameter of the circle was determined (Al-Suwayeh et al., 2014; Shinde et al., 2012).

Gelling time and gelling temperature

The Formulation's Gelling period will be measured using the pattern designated by Miller and Donovan. Before administration, the delivery system will get exist in a sol form, however, they administered once they undergoto gelled form to form a gel. Gelling period will be noted as the time for first discovery of gelation. The transition temperature of the produced gel formulation from sol to gel will get assessed by transferring the formulation of 2 ml to a 10 ml test tube and wrapped with para-film. This prepared tube waslocated in a circulatory watered bath at occasional temperature. According to those each temperature setting, equilibration was permitted for 10 minutes. As a conclusion, the tested

tube will set to be in horizontal position to detect the status of the sample produced and inspect the gelation.

The 90-degree temperature is the temperature when the gel formed because in that temperature a meniscus formulation would no longer move upon slanting the test tubes. To determine the gelation study, Miller and Donovan's technique was referred mostly. Using the certain technique the temperatureof gel formed was measured, that the test tube should have the stuff of enough amounts of the produced solutions, in a watered bath at 4ºC. The temperature of the Water bath willbe enlarged leisurely at a balanced rate of 1ºC at every 2 minutes of period (Miller and Donovan, 1982).

Viscosity of solution

Poly-herbal gel's viscosity was estimated by using viscometer. The gel formulations which have been prepared were transferred to the beaker. The spindle will be lowered upright into the gel at 100 rpm and maintained at occasional temperature. The viscosity was assessedthroughout the cooling of the system. The performance will be in triplicates for all the measurements(Shinde et al., 2008).

Results

3.1 Gel characterization

The formation of Box-Behnken design of each 17 gel formulations has been prepared. These gels were to be in smooth stuff and without any lumps. The appearance of all the formulations wassimilar to the brown in color with slight aromatic odor.

pH

The pH range should be 4.25 to 5.89 for all formulations which are in the series of nasal pH (4.5-6.4) (Nisha et al., 2012). The results exposed that all the equipped formulations are within the suitable pH range. Hence, a commonannoyance to nasal mucosa and further changes formed by the formulation could be evaded.

Viscosity

The gel's viscosity observed should be in the range of 4876 to 12560 cps. It was observed from the study of the results, that the gel's viscosity is augmented with the aggregate concentration of gellan gum. The gels viscosity was dependingformulation on the polymeric content (Shah et al., 2011). The occurrence of the combination of polymers considerable augmented the gel's viscosity.

Spreadability

The spreadability acts a major part in patient acquiescence and assists in when the gel was applied to the skin. A worthy gel proceedsfewer times to spread and it would results in high spreadability (Margaret et al., 1956).

Gelling temperature, gelling time and drug content

The temperature when the gel formed of the prepared gel ranged amid 32.15±0.34 and 36.12±0.82. The suitable temperature for the nasal gel ranged between 30-36ºC. In the present study, all the formulations exhibited the temperature when the gel formed within the range. The gelling time of the formulation ranged between 7±0.32 to 14±0.84. The drug stuff % of all the formulations was originated to be in the range of 90.61-97%.

Analysis of Contour plots and response surface methodology for the dependent and independent variables

Two-dimensional analysis of the contour and RSM plots were represented from the Figs. 1-6, in

order to identify the effects of interactions of factors with different responses. This helps in determining the relationship of the response (dependent variables) to that of the independent variables. The plots are essential for studying the effects of the two factors with that of the response. From the presented figures the third factor was taken constant and thus the relationships with two variables are non-linear (Viscosity and spreadability) although Fig. 3 representing a straight line (for temperature). Two-dimensional analysis of the contour and RSM plots were represented from the Figs. 1-6, in order to identify the effects of interactions of factors with different responses. This helps in determining the relationship of the response (dependent variables) to that of the independent variables. The plots are essential for studying the effects of the two factors with that of the response. From the presented figures the third factor was taken constant and thus from the relationships with two variables are non-linear (Viscosity and spreadability) although Fig. 3 representing a straight line (for temperature). From the Figs. 4-5 show that with the increase in the concentration of *Moringa olifera* (w/w%) and *Myrica nagi* (w/w%) represents curvilinear or nonlinear pattern. However Fig-6 (gelling temperature) showed linear representation (Straight line), as there is no considerable differences observed.

***In vitro* drug release study**

The *in vitro* drug discharge determination after elaborated studies consuming RSM based box-benken design. From the following studies four ideal formulations were objected to *In vitro* drug discharge study. The study was performed for the optimized formulation using phosphate buffer (6.4) as a medium. The conclusion results, the present studies in fig 1. The gel formulation was found to be secure in respect to the nasal administration.

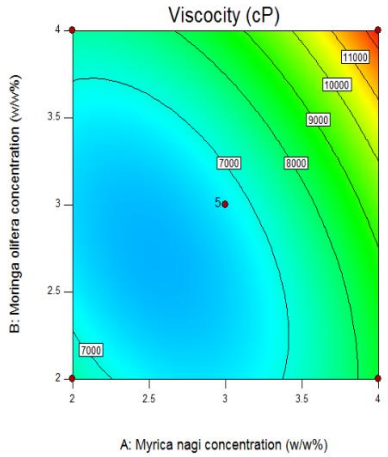

Fig. 1. Contour plot depicting effects of polyherbal concentration (X1,X2) on reponse Y1**.**

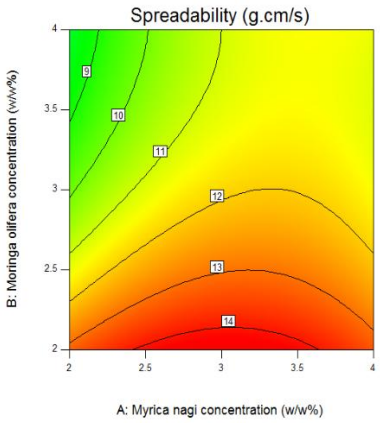

Fig. 2. Contour plot depicting effects of polyherbal concentration (X1,X2) on reponse Y2**.**

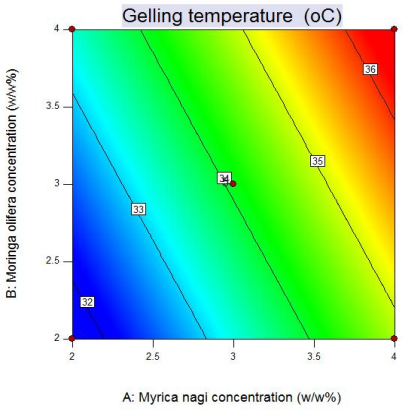

Fig. 3. Contour plot depicting effects of polyherbal concentration (X1,X2) on reponse Y1**.**

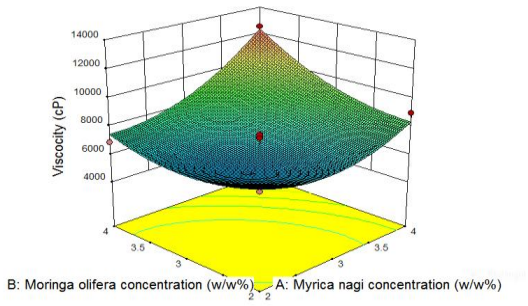

Fig. 4.RSM plot representing the effect of polyherbal gel concentration (X1&X2) on response Y1.

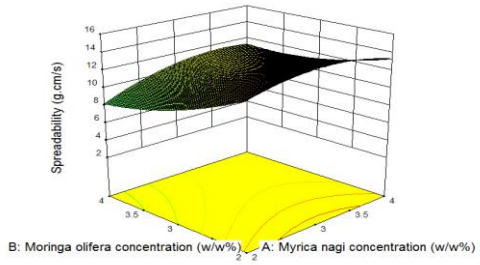

Fig. 5.RSM plot representing the effect of polyherbal gel concentration (X1&X2) on response Y2.

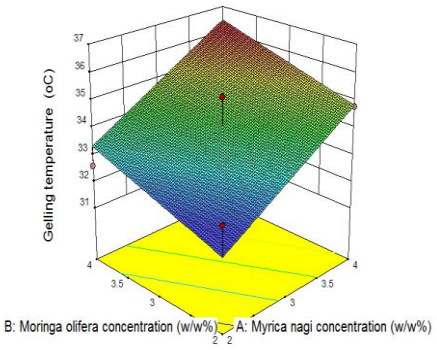

Fig. 6.RSM plot representing the effect of polyherbal gel concentration (X1&X2) on response Y3.

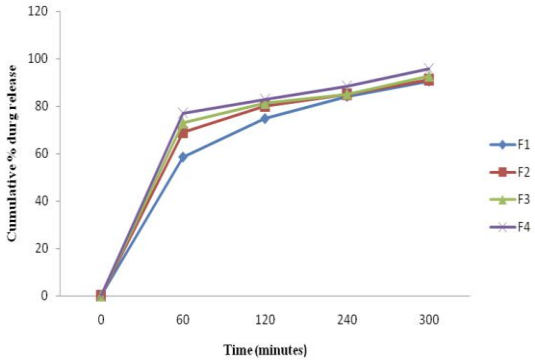

Fig. 7. In vitro release profiles of poly-herbal mucoadhesive gels for the ideal drug formulation.

Discussions

In recent yearsthe situ nasal gel dosage tends to serve as effective drug delivery systems, especially formeasured release of drugs that which makes an exact relief and also the gel helps in securing the active compounds from degradation due to external environmental conditions. The formulation of poly-herbal extracts (*Myrica nagi* and *Moringa olifera*) using both synthetic as well as natural polymers found to be effective. Some of the key factors such as viscosity, spreadability and gelling temperature affects the drug delivery of the gel synthesized (Sherafudeen et al., 2015). Using RSM methodology involving Box-

Behnken approach (three level three factorial) we determined the essential dosage formulation (F1-F4) (Chaudhary et al., 2011). The formulations were subjected to in-vitro drug release F1 exhibited controlled/prolonged drug release (90.61%) associated to other formulations (F2- 91.25%, F3- 92.67% and F4- 95.68%) with a measured drug discharge for an overall period of 6 hrs.

Conclusion

In recent years the situ nasal gel dosage tends to serve as effective drug delivery stems, especially for measured release of drugs that which makes an exact relief and also the gel helps in securing the active compounds from degradation due to external environmental conditions. The formulation of poly-herbal extracts (*Myrica nagi* and *Moringa olifera*) using both synthetic as well as natural polymers found to be effective.

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