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RESEARCH ARTICLE
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FORMULATION AND EVALUATION OF A POLYHERBAL SUSPENSION OF ALOE BARBADENSIS (EEAB), SALIX TETRASPERMA(EEST) AND TENACETUM PARTHENIUM (EETP)

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Abstract:
Aim: The present study was conducted in order to carry out in order to formulate a polyherbal suspension produced from ethanolic extract of Aloe barbadensis (EEAB), Salix tetrasperma (EEST) and Tenacetum parthenium (EETP) leaves.

Methods: The polyherbal suspension produced from ethanolic extract of Aloe barbadensis (EEAB), Salix tetrasperma (EEST) and Tenacetum parthenium (EETP) leaves was formulated and evaluated for the accelerated stability for around 3 months.

Result: Polyherbal formulation-SF 4 shows the perfect appearance and texture; there were no changes in sedimentation rate, pH, flow rate, viscosity and various other physiochemical parameters. All the quality control parameters in formulated suspension were found to be holistic and acceptable.

Conclusion: It is concluded that suspension of ethanolic extracts of Aloe barbadensis (EEAB), Salix tetrasperma (EEST) and Tenacetum parthenium (EETP) leaves, so formulated could be effective and safe and suitable for use.

Key Words: Polyherbal formulation, Suspension, Quality Evaluation, Stability testing.

INTRODUCTION:

The oral administration method is one of physical administration methods. In general, the parenteral route is not suitable for self-administration. Most of the drugs that use to produce therapeutic effects, appears to be given orally (1). Liquid medicine has some limitations, but the public has a great need or expectation for these formulations. In addition, some designs are more effective in liquids and are often used by children or adults to overcome problems with swallowing oral materials. Most oral

herbal preparations are liquid or herbal preparations. The design and manufacture of oral herbal liquid formulations is far from competing in the modern pharmacy (2).

MATERIALS AND METHODS:

Collection of Plant materials

Plant materials Aloe barbadensis and Salix tetrasperma was collected from Karond Bypass Road, Bhopal and Tenacetum parthenium was collected from Rutvik enterpises, Vasai West, Maharashtra. Special precaution was taken to collect healthy plant materials and foreign materials were avoided. Herbarium of plants were prepared and submitted to Department of Botany, Safia Science College, Bhopal, M.P.) for authentication. Plants were authenticated by Botanist Dr. Saba Naaz, Department of Botany, Safia Science College, Bhopal, M.P.) Plant authentication voucher number obtained was 173/Saif/Sci./College/Bpl for Aloe barbadensis, 174/Saif/Sci./College/Bpl for Salix tetrasperma and175/Saif/Sci./College/Bpl for Tenacetum parthenium correspondingly.

Preparation of extracts

The extraction using the method of percolation in which dried plant sample was kept in contact with organic solvents such as ethanol for around 8-10 hours at 40-60^{o}C temperature, in the thimble part of the Soxhlet apparatus. As soon as the extraction process completes, the extract was filtered, allowed to dry and percentage yield was calculated. Extracts were collected in air tight container till further user (3)**.**

Preparation of Polyherbal Suspension Dosage Form

The polyherbal suspension of Ethanolic extract of Aloe barbadensis (EEAB), Salix tetrasperma (EEST) and Tenacetum parthenium (EETP) leaves (1:1:1) were prepared by trituration method. Other excipients such as sodium carboxymethyl cellulose (CMC), Tween 80, flavoring agent, sweetening agent, lemon oil, sodium benzoate and distilled water were added. The polyherbal suspension was evaluated for its Organoleptic properties.

The physicochemical parameters studied were sedimentation volume, redispersibility, pH, density, flow and viscosity (using Brookfield viscometer type III using spindle 2 at 250 rpm). The formulation was kept at room temperature (35±10°C) for one year. Its physicochemical parameters were again examined. With the help of Design Expert software (DOE) formula for herbal polyherbal suspension was optimized (4) (Table 1).

Table 1: Composition of optimized herbal suspension formulation

S.N.	Chemical required	Quantity taken (SF 4)
1	*Aloe barbadesis , Salix tatrusperma* and *Tenocetum Parthenium* (1:1:1)	3 gm
2	Tween 80	1.250 ml
3	Sodium CMC	0.750 gm
4	Sodium Benzoate	0.5 gm
5	Sorbitol	1%
6	Lemon oil	0.7 ml
7	Purified water q.s.	100 ml

QUALITY PARAMETERS OF POLYHERBAL SUSPENSION

Organoleptic Properties of herbal polyherbal suspension

The polyherbal suspension was evaluated for its Organoleptic properties such as colour, odour, taste and texture etc (2).

Determination of viscosity

The viscosity of polyherbal suspensions were determined using Brookfield viscometer type III using spindle 2 at 250 rpm. All determinations were carried out in triplicates and results obtained were expressed as the mean values (4).

Redispersibility

A constant volume (50 ml) of each plant suspension was stored in calibrated tubes kept at room temperature for different periods (1, 5, 10, 15, 20, 30, 45 days). Periodically remove a tube and shake vigorously to redistribute the sediment and record the presence of any sediment. (5).

Flow rate (F)

Determination of the time taken by the 10 ml sample of herbal suspension to flow through the 10 ml pipette was carried out to check the flow rate and calculation was done using the formula below (2):
$F = Volume\ of\ pipette\ (ml)/Flow\ time\ (sec)$

Determination of pH

The pH of polyherbal suspension was determined by using the pH meter (4).

Degree of flocculation

Degree of flocculation (β) was determined using following equation (2).

$$\beta = (Vu)/(Vu)defloc$$

Where, (Vu) means the floc is ultimate sedimentation volume in flocculated polyherbal suspension and (Vu) means the defloc is ultimate .Sedimentation volume in deflocculated polyherbal suspension.

Sedimentation volume

The sedimentation volume is the ratio of the final height (Hu) of the sediment to the initial height (Ho) of all the plants removed when plants are removed in several cylinders according to standard procedure. The volume of the multi-drug suspension is determined by measuring the height in a graduated cylinder for a specified period of time, and the maximum indicated residue volume is recorded. (4).
$F=Hu\ /\ Ho$

STABILITY PARAMETERS FOR POLYHERBAL SUSPENSION

Accelerated stability study

In accelerated stability testing, the product is challenged at several high temperatures (higher than average temperature) and the energy required to make the product is not taken into account. This is done by the product according to rapid degradation conditions. These data are then estimated to estimate shelf life or compare the relative stability of other formulations. This often provides an early indication of product shelf life and reduces development time (5).

Crystal growth

The stability of polyherbal suspensions can also be reduced by crystal growth, which usually occurs during storage due to changes in temperature and forming a small size. Crystal formulations were determined at 4°C, room temperature (RT), and 47°C. (5).

RESULTS AND DISCUSSION

The different parameters such as viscosity, sedimentation volume, flow rate, redispersibility, and crystal growth were evaluated for the formulation.

Organoleptic Properties of herbal polyherbal suspension

The Polyherbal formulation was found to be liquid in nature, slightly bitter taste, light shade in colour and pleasant odour (Table 2).

Table 2: Organoleptic Properties of herbal polyherbal suspension

S.No.	Parameter	Optimized Formulation code SF 4
1.	Nature	Liquid
2.	Color	Light
3.	Odor	Pleasant
4.	Taste	Slightly bitter
5.	Texture	Suspension

Determination of viscosity

Viscosity shows a decrement with respective to the increment in the rpm which indicates the shear thinning nature of suspension (Table 3).

Redispersibility of optimized formula

Since the suspension will remain during storage, it must have radial dispersibility to provide a large amount after agitation. If residue remains after vigorous agitation, the suspension is termed clumped. After 45 days, all suspensions were found to be readily redispersible for up to 20 shakes (Table 3). The redispersibility of the suspension was found to be faster for the lower amount of suspending agent compared to higher concentrations. This can be attributed to the higher viscosity of the suspension.

Flow rate (F) of optimized formula

It was found that the flow rate decreased with increasing suspension agent and suspension viscosity. The flow rate of the suspension was found to be as a function of time at 5 mL/5.64 sec, which is between 0.1-0.5. It is found shown in the Table3.

Determination of pH

pH of all formulation was found to be in the range of 6.640 ±0.54 (Table3).

Degree of flocculation of optimized formula

The degree of flocculation of all formulation suspensions was determined using different concentrations of suspensions containing extracts of the optimized formulation SF4. This is due to the high viscosity of the suspension at higher concentrations, which will ultimately reduce the suspension problem. (Table 3)

Sedimentation volume of optimized formula

At the end of 7 days, a decrease in sedimentation was observed. The optimized system was stable and broke after 45 days. Particles dispersed more rapidly in a suspension containing a lower concentration of suspending agent than in a suspension containing a higher concentration of suspending agent (Table3).

Table 3: Evaluation parameters of optimized formula SF 4

S.No.	Parameter	Optimized Formulation code SF4
1.	Viscosity	156.64cp
2.	Redispersibility (index)	1 inversion (very good)
3.	Flow rate	0.15 cm^3
4.	pH	6.640 ±0.54
5.	Sedimentation volume	0.30± 0.26(ml)

6.	Degree of flocculation	3.45±0.38

STABILITY PARAMETERS FOR POLYHERBAL SUSPENSION

Accelerated stability study

The optimized formulation was packed and placed in the stability test chamber which were later subjected to stability studies at accelerated testing (250C ± 20C and 60 ± 5% RH) and (400C ± 20C and 70 ± 5% RH) for 3 months. The formulation was checked for Viscosity, crystal growth, redispersibility, pH, and degree of flocculation at the interval of 30, 45, 60, 90 days (3 month) months. The formulation was tested for stability under accelerated storage condition for 3 months in accordance to International Conference on Harmonization (ICH) guidelines. Formulation was analyzed for the change in particle size, entrapment efficacy and in-vitro drug release studies. All Results were compared against final formulation of 0 days as the reference (Table 4). The selected optimized formulation was evaluated for stability studies which were stored at temperature of 25° ± 2°C and 60%± 5% RH and 400C ± 2 0C and 70 ±5% RH for 90 days (3 month) .There was no significant change in the properties of oral suspension formulation SF 4 during the stability period. There was a slight increase in particle size and entrapment for the stored formulation, but it was well within the acceptable limit.

Crystal growth of optimized formula

Stability of suspension can also be reduced by crystal growth, which usually occurs due to temperature changes during storage, improving the size distribution. (Table 5)

CONCLUSION

Polyherbal suspensions were prepared and evaluated for various stability parameters. The World Health Organization guidelines has set up the guidelines regarding the evaluation of the parameters, which made it mandatory to follow the instructions for developing herbal products for various ailments and diseases. Furthurmore, pharmaceutical formulation such as suspensions needs some excipients other than the active pharmaceutical ingredients such as preservatives, flavouring agents coloring etc. Selection of a proper excipient plays a crucial role in stability and efficacy of the formulation because there is a physical compatibility among the active part and excipient of a formulation. In our study, we had selected Sorbitol (sweetening agent) and Tween 80 polysorbate (surfactant) which also increases the bioavailability of the active drug due to its non-ionic nature and it does not alter the pH of the suspension. Other excipient such as Sodium CMC enhances the stability of suspension by improving the viscosity. Also, Lemon oil and Sodium benzoate was used as a flavoring agent and preservative, respectively. All the excipients used in our study was all non-toxic shows a good compatibility with the active drug contents. The prepared suspension formulation SF 4 was found to have very good and excellent redispersibility property, which indicates that the formulation was optimum and acceptable. All formulations were found to be stable and effective to varying degrees. No significant changes were observed in physicochemical and stability parameters.

Conflict of interest: none

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Table 4: Accelerated Stability Study of optimized formulation SF 4

S. N	Time (Days)	25^0C±2 ^{0}C and 60 ± 5% RH				40^0C±2 ^{0}C and 70 ±5% RH			
		Viscosity	Redispersibiliy	pH	Degree of flocculation	Viscosity	Redispersibility	pH	Degree of flocculation
1.	0	95 cp	1 inversion	6.79	3.45±0.38	95 cp	1 inversion	6.79	3.45±0.38
2.	30	95.2	1 inversion	6.79	3.46±0.39	95.5	1 inversion	6.79	3.46±0.39
3.	45	95.3	1 inversion	6.78	3.46±0.39	95.6	1 inversion	6.77	3.47±0.39
3.	60	95.4	1 inversion	6.78	3.49±0.40	95.7	1 inversion	6.76	3.49±0.40
4.	90	95.5	1 inversion	6.77	3.49+±0.4	95.7	1 inversion	6.76	3.49+±0.40

Table 5: Crystalformationof optimized formulation

S.No.	Optimized Formulation code	Time duration (hrs)	Temperature (°C)	Crystal formation
1.	SF 4	24	4°C RT 47°C	No No No
1.	SF 4	48	4°C RT 47°C	No No No
1.	SF 4	72	4°C RT 47°C	No No No