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FORMULATION AND EVALUATION OF POLYHERBAL CAPSULES CONTAINING *SAUROMATUM GUTTATUM* (WALL.) SCHOTT TUBERS AND LEAVES EXTRACTS

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ABSTRACT

Medicinal plants are commonly known for their medicinal value and free from adverse effects. The aim of the study is to formulate and evaluate the polyherbal capsules containing *Sauromatum guttatum* (Wall.) Schott tubers and leaves extracts. Scanning and determination of maximum wavelength (λmax) has been recorded. Preformulation parameters such as bulk density, tap density, Carr's index, Hausner's ratio, and angle of repose were reported. Preparation of polyherbal formulation (PHF) has been done and quality of formulation was tested as stated by the WHO guidelines for quality control of herbal materials. Then evaluation of the formulated herbal capsules for their organoleptic characters, moisture content, pH, weight variation, disintegration time, drug content, drug release and microbial load has been done. After that it was compared with Indian pharmacopoeial standards. Future possibilities incorporate the clinical trials of the final product as the clinical viability is as of now demonstrated in various creature considers.

Keywords: Polyherbal, preformulation, organoleptic, disintegration

INTRODUCTION

World Health Organization (WHO) has cleared medicinal products based on finite medicinal herbs labeled with active ingredients, aerial or subterranean parts of

the plant or other materials or mixtures of plants. Formulations which contain at least two natural medications with different pharmacological activity remedial impact are called as poly herbal formulation. It contains either two or more than two herbal medicines and each medicine has different chemical constituents, so the herbal formulations contain a large number of phytochemical constituents **[1]**.

Herbal formulations have gained widespread acceptance as therapeutic agents for diabetics, arthritis, liver diseases, cough remedies and memory stimulators **[2]**. Because of the therapeutic properties attributed to a rough drug, it is important to maintain its quality and virtue in the showcase of the company. It is, however that the medications in business are as often as possible contaminated and don't consent to the norms recommended for bonafide drug **[3]**. Most traditional medical systems are effective but lack standardization, so it is necessary to develop a standardization technique. The Central Council of Research in *Ayurveda* and *Siddha* has provided preliminary guidelines to standardize these conventional formulations. For the uniformity of batches in the production of herbal formulations it is important to create evaluation techniques. The standardization of drugs implies the affirmation of their identity and the guarantee of their quality and purity. Initially, the raw drugs were recognized only in comparison with the standard description available. Currently, due to the expansion of the chemical awareness of raw drugs, various methods are used, such as botanical, chemical, spectroscopic and biological methods to estimate the active components present in crude drugs as well as their physical constants **[4]**.

The present study was aimed to continue this research by undertaken to formulate the herbal capsules using the tubers and leaves extracts of *Sauromatum guttatum* (Wall.) Schott and evaluated the pharmaceutical quality of herbal capsules formulated.

MATERIALS AND METHODS

Selection, collection and authentication of plant/plant material

The plant parts were gathered in the month of July-September 2016 from the different local sites of Rewa and Jabalpur areas of M.P. and identified & authenticated by Dr. S. N. Dwivedi, Prof. and Head, Department of Botany, Janata P.G. College, A.P.S. University, Rewa, M.P. and then it was deposited in our laboratory, voucher specimen No. PCog/SG/16.

Successive extraction of plant material

Both parts (tubers and leaves) samples were shattered and screened with 40 mesh. The shade dried coarsely powder of tubers and leaves of *Sauromatum guttatum* (Wall.) Schott (250 gm) were stacked in Soxhlet apparatus and then extracted with petroleum ether (60-62°C), chloroform, ethanol and water until the extraction was not finished. The solvent was removed by distillation after fruition of extraction. The extracts were dried with the help of rotator evaporator. The residue was then put away in desiccator and percentage yield were determined **[5]**.

Formulation of dosage form

Preparation of polyherbal formulation (PHF)

The formulation (capsules) contained the AESGT, EESGT, AESGL & EESGL extracts were prepared in the varied ratio (as mentioned in **Table 3 to 6**). The quality of formulation was tested as stated by the WHO guidelines for quality control of herbal materials. As stated by the guidelines, specific powder characteristic examinations just as angle of repose, bulk density, tapped density and so on were undertaken and significant results were recorded.

Scanning and determination of maximum wavelength (λmax)

100 mg of AESGT, EESGT, AESGL & EESGL extracts were dissolved in suitable solvent (Phosphate buffer pH 7.4) to prepare stock solution of 1000 µg/ml for determination of the wavelength of maximum absorption of the extracts. From this different concentrations of 10, 20, 30, 40 and 50 µg/ml were prepared and scanned using the spectrophotometer in the wavelength range of 400-200 nm compared to Phosphate buffer pH 7.4 as blank and the wavelength corresponding to the maximum absorbance were recorded to determine the λmax.

Preformulation studies

Preformulation parameters for example bulk density, tap density, Carr's index, Hausner's ratio, and angle of repose were reported for laboratory granules.

Bulk density

Bulk densities were established by poured gently 25 gm of the sample through glass funnel into a 100 ml graduated cylinder. The volumes occupied by the sample were noted carefully. Bulk density was calculated by t using the following formula:

Bulk density (g/ml) = weight of sample in gms/ volume occupied by the sample

Tapped density

Tapped densities were determined by pouring gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. The

cylinder was tapped from height of 2 inches until a constant volume was obtained. Volume occupied by the sample after tapping was recorded and tapped density was calculated too.

Tapped density (g/ml) = weight of sample in gms/ volume occupied by the sample

Compressibility index

It is also one of the easiest or trouble-free methods for evaluation of flow property of powder by comparing the bulk density and tapped density. A valuable empirical guide is given by the Carr's compressibility.

Carr's index= TD-BD/TDX100

Hausner ratio

It presents an indication of the degree of densification which could result from the feed hopper vibration.

Hausner ratio = Tapped density/ Bulk density
Lower Hausner ratio = Better flow ability, Higher Hausner ratio = Poor flow ability

Angle of repose

Flow properties of the physical mixtures of all the formulations were determined by calculating angle of repose by fixed height method. A funnel with 10 mm inner diameter of stem was fixed at a height of 2 cm. over the platform. Approximately 10 gm of sample was passed slowly along the boundary wall of the funnel till the tip of the pile formed and touches stem of the funnel. A rough circle was drawn around the pile base and the radius of powder cone was deliberated. Angle of repose was calculated from average radius using following formula.

$$\tan \theta = h/r$$

Where, θ = Angle of repose, h = Height of the pile, r = Average radius of powder cone

Preparation of formulation (Capsule) by Wet granulation method

The formulation preparation began with trials by including a variety of ratio of binders and choosing the extent of lubricants and preservatives and ultimately the procedure was optimized. AESGT, EESGT, AESGL & EESGL extract were finely powdered (sieve 40), and mixed in the proportion as referenced in **Table 3 to 6**. what's more, taken for preparation of capsules by wet granulation technique utilizing lactose solution as a binder. The wet mass was passed through sieve no. 22 to acquire granules. In a tray dryer, the granules were dried at 45°C. With magnesium stearate, the granules were lubricated or greased up. Diluents and preservatives were included. After this, the granules from the optimized batch were filled up in capsules coloured yellow-red of size "0" in a capsule filling machine. The capsules were then deducted and moved into poly bags, labelled. After that samples were evaluated as per testing requirements. Every 500 mg of herbal capsule contained the extracts of AESGT, EESGT, AESGL & EESGL and lactose and

excipients: quantity sufficient (q. s.) as given in **Table 3 to 6**.

Table 1: Grading of powders for their flow properties

Consolidation index (Carr's index)	Flow
5-15	Excellent
15-16	Good
*18-21	Fair to Passable
*23-35	Poor
33-38	Very poor
<40	Very Very poor

Table 2: Relationship between angle of repose (θ) and powder flow

Angle of repose (θ)	Type of flow
<25	Excellent
25-30	Good
*30-40	Passable
>40	Very poor

*Adding the glidant e.g. 0.2% aerosol, may improve flow

Table 3: Preparation of herbal capsule containing extract of AESGT

S. No.	Ingredients	Quantity (in mg)						
		F1	F2	F3	F4	F5	F6	F7
1.	AESGT	125	175	325	350	375	425	450
2.	Lactose	200	100	100	50	75	25	25
3.	Magnesium state	100	200	50	50	25	25	12.5
4.	Preservatives	75	25	25	50	25	25	12.5
	Net Weight	500	500	500	500	500	500	500

Table 4: Preparation of herbal capsule containing extract of EESGT

S. No.	Ingredients	Quantity (in mg)						
		F1	F2	F3	F4	F5	F6	F7
1.	EESGT	125	175	325	350	375	425	450
2.	Lactose	200	100	100	50	75	25	25
3.	Magnesium state	100	200	50	50	25	25	12.5
4.	Preservatives	75	25	25	50	25	25	12.5
	Net Weight	500	500	500	500	500	500	500

Table 5: Preparation of herbal capsule containing extract of AESGL

S. No.	Ingredients	Quantity (in mg)						
		F1	F2	F3	F4	F5	F6	F7
1.	AESGL	125	175	325	350	375	425	450
2.	Lactose	200	100	100	50	75	25	25
3.	Magnesium sterate	100	200	50	50	25	25	12.5
4.	Preservatives	75	25	25	50	25	25	12.5
	Net Weight	500	500	500	500	500	500	500

Table 6: Preparation of herbal capsule containing extract of EESGL

S. No.	Ingredients	Quantity (in mg)						
		F1	F2	F3	F4	F5	F6	F7
1.	EESGL	125	175	325	350	375	425	450
2.	Lactose	200	100	100	50	75	25	25
3.	Magnesium sterate	100	200	50	50	25	25	12.5

4.	**Preservatives**	**75**	**25**	**25**	**50**	**25**	**25**	**12.5**
	Net Weight	**500**	**500**	**500**	**500**	**500**	**500**	**500**

Evaluation of capsule

Evaluation of the formulated herbal capsules for their description, microbial load, uniformity of dosage units, weight variation, disintegration time and moisture content has been done. After that it was compared with Indian pharmacopoeial standards.

Organoleptic characters

The PHF (Capsule) were examined for their colour and appearance. The colour, odour, taste were observed and noted down.

Moisture content

With the help of automatic Karl Fischer titration apparatus, moisture content was determined.

pH

The pH was determined with the help of pH meter.

Weight variation

Capsules, in numbers of quantity 20 were individually weighed and average weight of the capsule was calculated. The individual weights of the each of the capsule should be within limits of 90% and 110% of average weight.

Disintegration time

Disintegration test was executed by utilizing the digital microprocessor based disintegration test apparatus (Electro lab, Mumbai, India). One capsule was introduced into each tube and a disk was added to each tube. The assembly was suspended in water in 1000 ml beaker. The volume of the water at its highest point was at least 25 mm below the surface of the water and at its lowest point was at least 25 mm above the bottom of the beaker. The apparatus was operated and maintained at a temperature of 37 ± 2°C.

Drug content

Five randomly chosen capsules were weighed, evacuated the cap and body and were powdered. The powdered equivalent to 100 mg drug in one capsule was taken and moved in 100 ml flask which contain 100 ml of 0.1 N HCl having pH 1.2. The flask was shaken on a flask shaker and was kept for couple of hours for the sedimentation of un-dissolved materials. The solution is filtered through whatman filter paper. 10 ml of this filtrate was taken and suitable dilution was made. The samples were examined at explicit wavelength with the help of UV visible spectrophotometer. The drug content was resolved from standard curve prepared at optimum λ max.

Drug release

Drug release was estimated by dissolution test under the accompanying conditions: n = 6 (in triplicate), USP type II dissolution apparatus (Lab India, DISSO 2000) at 50 rpm in 900 ml of 0.1 N HCl pH 1.2 kept up

at 37 ± 0.5˚C. The capsule was permitted to sink to the bottom of flask before stirring. Exceptional safety measure was taken not to form air pockets on the outside of tablet. 5 ml of the sample was pulled back by utilizing a syringe filter at ordinary interims and supplanted with a similar volume of pre warmed (37 ± 0.5°C) new dissolution medium. The drug content in each sample was examined after proper dilution with the help of UV spectrophotometer method at respective maximum wave length.

Microbial load analysis

Microbial count was accomplished for the protected use or safe utilization of the herbal capsules and it was checked whether the absolute aerobic viable count, yeasts and molds were within the prescribed restrictions and the microorganisms *Escherichia coli, Clostridia*, *Salmonellae*, *Shigella, Pseudomonas* and *Staphylococcus* were missing or absent in the final (optimized) formulation **[6-9]**.

RESULTS AND DISCUSSION

Scanning for λmax of Poly Herbal Extract

For UV scanning for λmax of extract, about 100 mg of poly herbal extract was weighed and transferred to a 100 ml volumetric flask containing 0.1 N HCl solution and shaked to dissolve and volume was made to 100 ml. Then 10 ml of this solution was diluted to 100ml to obtain a solution of 100 µg/ml and further diluted to obtain 10, 20, 30, 40 and 50 µg/ml and scanned for λmax taking 50 µg/ml. From the curve, peaks for the poly herbal extract were determined. pH extract showed maximum absorption at 278 **(Figure 1)**.

Standard curve of extract

Standard calibration curve of poly herbal extract was determined by plotting graph between absorbance v/s concentration on double beam U.V. spectrophotometer using λmax at 278 nm & it follows the Beer's law. Straight line was obtained after plotting absorbance on X axis and concentration on Y axis. The line of equation was found to be Y= 0.001X+0.002. The R^2 value was found to be 0.994. The result was shown in **Table 7 and Graph 1**.

Preformulation studies

Preformulation parameters such as bulk density, tap density, Carr's index, Hausner's ratio and angle of repose were studied and investigated for the granules. The results are presented in **Table 8**.

Evaluation of PHF (Capsule)

The polyherbal capsules (AESGT, EESGT, AESGL & EESGL) and optimized formulation AESGT were evaluated for their description, microbial load, uniformity of dosage units, weight variation, disintegration time, and moisture content, and compared

with Indian pharmacopoeial standards. The results for various formulation i.e., F1 to F7 were presented in **Table 9**. From the detailed result it was found that the formulation code, F5 is showing better results as compared to other formulation codes. Microbial load analyses of final optimized formulation were reported in **Table 10**.

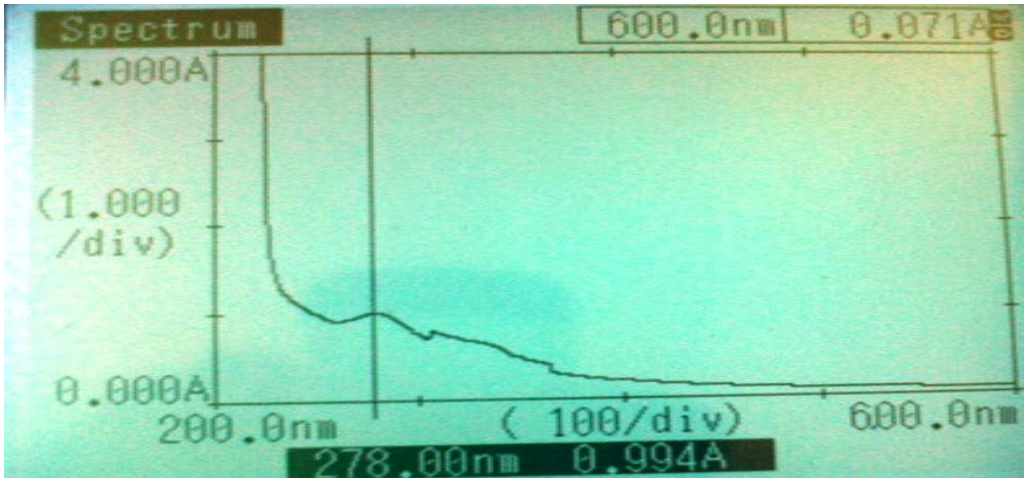
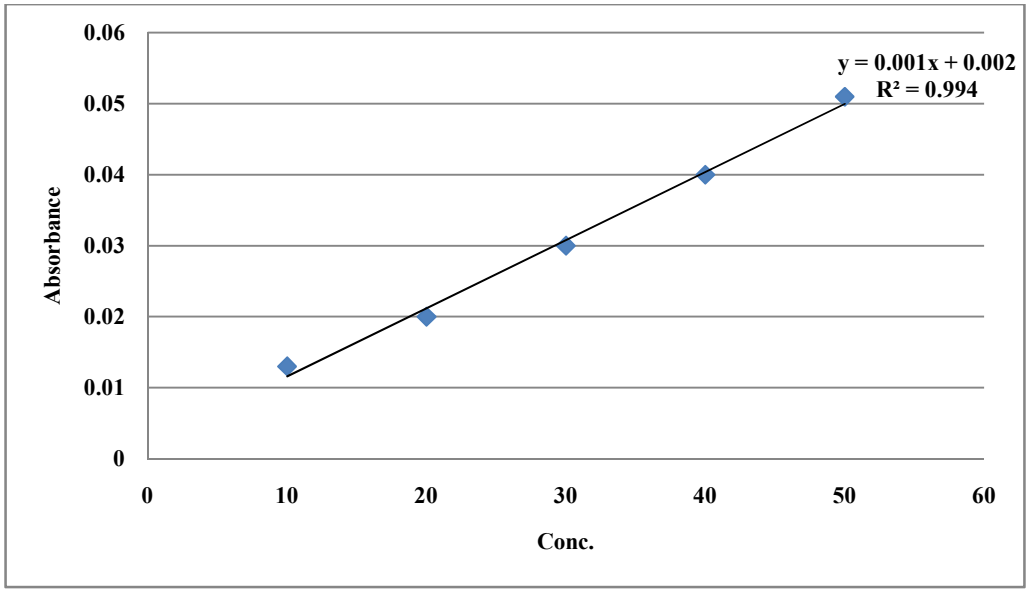


Figure 1: λmax of Poly Herbal Extract

Table 7: Absorbance of Poly Herbal extract at λmax 278

S. No.	Conc. (µg/ml)	Absorbance(nm)
1.	10	0.013
2.	20	0.020
3.	30	0.030
4.	40	0.040
5.	50	0.051



Graph No. 1. : Standard Curve of Poly Herbal extract at λmax 278

Table 8: Preformulation studies and results of flow properties

S. No.	Parameters	Results						
		F1	F2	F3	F4	F5	F6	F7
1.	Bulk Density	0.923	0.813	0.728	0.649	0.615	0.772	0.805
2.	Tapped Density	0.746	0.704	0.634	0.583	0.549	0.706	0.690
3.	Carr's Index	23.72	15.48	14.82	11.32	12.02	9.34	16.66
4.	Hausner's Ratio	0.808	0.865	0.870	0.898	0.892	0.914	0.857
5.	Angle of Repose	27.13	31.62	24.92	23.62	21.45	30.13	28.10

Table 9: Evaluation of PHF (F1 to F7): Capsule (AESGT)

S. No.	Evaluation Parameters	Observations						
		F1	F2	F3	F4	F5	F6	F7
1.	Colour	Light Green	Light Green	Light Green	Dark Green	Dark Green	Dark Green	Dark Green
2.	Odour	Characteristics	Characteristics	Characteristics	Characteristics	Characteristics	Characteristics	Characteristics
3.	Taste	Bitter	Bitter	Bitter	Bitter	Bitter	Bitter	Bitter
4.	Nature	Powder granules	Powder granules	Powder granules	Powder granules	Powder granules	Powder granules	Powder granules
5.	Size of capsule	0	0	0	0	0	0	0
6.	Colour of Cap	Light Brown	Light Brown	Light Brown	Light Brown	Light Brown	Light Brown	Light Brown
7.	Colour of body	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown	Dark Brown
8.	Moisture Content	1.15% w/w	1.09% w/w	1.05% w/w	0.98% w/w	0.94% w/w	1.02% w/w	1.13% w/w
9.	pH	6.9	7.1	7.0	7.3	7.3	7.3	7.2
10.	Average Weight	750 mg	750 mg	750 mg	750 mg	750 mg	750 mg	750 mg
11.	Weight Variations	690-780 mg	700-770 mg	735-780 mg	738-772 mg	740-758 mg	730-775 mg	725-790 mg
12.	Disintegration Time	10 min 30 sec	09 min 10 sec	07 min 30 sec	06 min 40 sec	04 min 40 sec	10 min 10 sec	12 min 10 sec
13.	Drug Content	90.44	93.41	96.59	98.31	99.87	97.32	89.81
14.	Drug Release (30 mts)	87.14	90.18	94.20	96.62	97.42	94.40	84.78

Table 10: Microbial Load analysis of Final optimized formulation (F5)

S. No.	Parameters	Observations
1.	Total Microbial count (NMT 1000 cfu/g)	109
2.	Yeast and Moulds	Nil
3.	Presence of *E. coli*	Absent
4.	Presence of *Salmonella*	Absent
5.	Presence of *Streptococcus*	Absent
6.	Presence of *Pseudomonas*	Absent

Figure 2: Prepared PHF-F5 (Capsule): Final optimized formulation

CONCLUSION

As per the outcomes of pharmacological screening extracts viz., AESGT, EESGT, AESGL & EESGL were selected for formulation of herbal capsule. The λmax (maximum wavelength) were recorded it and was found to be 278 nm. Standard curve were plotted and regression coefficient were determined. Preformulation studies were determined for all physical mixtures. The results of angle of repose, Carr's Index and Hausner ratio indicated that the powder mixtures possess good flow properties and good packing ability. The polyherbal capsules (AESGT, EESGT, AESGL & EESGL) and optimized formulation AESGT have been evaluated for their description, microbial load, uniformity of the dosage units, weight variation, disintegration time and moisture content and compared to the Indian pharmacopoeial standards. The different composition of the prepared herbal capsule formulations was provided. The physical property of capsule was observed and the results of the uniformity of weight, drug content etc. of the capsules was given. All the samples of the test product met the terms with the official requirements of uniformity of weight. The drug content was found to be close to 100% in all formulations. On the basis of results obtained after evaluation of herbal capsule one optimized formulations i.e., F5 of AESGT is found best.

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