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Formulation, Development and Evaluation of SEDDS of *Andrographic Paniculata* Plant Extract

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KEYWORDS

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ABSTRACT:

Leave and aerial (whole parts) of Andrographic paniculata have anti-inflammatory and antidiabetic efficacy. However, the clinical translation of plant extracts is often hindered by poor aqueous solubility and low oral bioavailability,. The Self-Nanoemulsifying Drug Delivery System (SNEDDS) offers a promising approach to overcoming these limitations by enhancing solubility, stability, and gastrointestinal absorption of lipophilic phytoconstituents.

In order to increase Andrographic paniculata extract's solubility, in vitro dissolving efficiency, and bioavailability, the current work set out to design a self-emulsifying drug delivery system (SEDDS). Andrographic paniculata extract's solubility in a range of oils, surfactants, and co-surfactants was assessed. The prepared SEDDS was assessed for stability, in vitro dissolution, drug content, and emulsification time. Maximum solubility, reduced emulsification time, good stability, and enhanced in vitro release were all demonstrated by the optimized formulation. In this investigation, data was imported using pre-existing historical data.

Introduction

Herbal medicines have formed the foundation of traditional healthcare systems such as Ayurveda, Unani, and Traditional Chinese Medicine for thousands of years. Plant-derived extracts are rich sources of bioactive secondary metabolites and have attracted increasing scientific interest due to their broad spectrum of pharmacological activities, favorable safety profiles, and natural origin. In recent years, the global demand for herbal and phytopharmaceutical products has grown substantially, driven by rising concerns over the side effects of synthetic drugs and a preference for natural therapeutics. However, despite their proven biological potential, the successful clinical translation of many herbal extracts remains limited. Around 60% of herbal new drug candidates have less solubility, and the oral deliveries of such drugs are associated with low bioavailability. One of the primary challenges associated with herbal therapeutics is their poor aqueous solubility, chemical instability, and low oral bioavailability. Many phytoconstituents exhibit lipophilic characteristics, leading to slow dissolution in gastrointestinal fluids and poor absorption across the intestinal epithelium. Additionally, factors such as degradation in acidic gastric conditions, extensive first-pass hepatic metabolism, and efflux by intestinal transporters further reduce systemic availability. As a result, higher doses are often required to achieve therapeutic efficacy, which may increase variability in pharmacokinetic response and limit patient compliance. To overcome these problems, various formulation strategies are exploited including the use of surfactants, lipids, permeation enhancers, and micronization. Majority of these approaches have their limitations because of the need for specialized equipment, complicated manufacturing process, longer processing time, and regulatory complexity. Lipid-based formulation approaches, particularly the self-emulsifying drug delivery system (SEDDS), are well known for their potential as an alternative approach for delivery of hydrophobic drugs, which are associated with poor water solubility and low oral bioavailability.SEDDS is among the methods used to improve the oral bioavailability of poorly soluble drugs by presenting and maintaining the drug in a dissolved state, in small droplets of oil, all over its transit through the gastrointestinal tract (GIT).

SEDDSs are the isotropic mixtures of oil, surfactant, cosurfactant, and drug which form oil in water microemulsion. These formulations spread readily in

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the GIT, and the digestive motility of the stomach and intestine the agitation necessary for self-emulsification. In a good self emulsifying system, small emulsion droplets containing dissolved drug are formed on contact with the gastrointestinal fluid. The drug in the fine emulsion droplets is exposed to a large interfacial area, thus allowing for greater diffusion through the membrane to take place. [1-7]

Formulation of self emulsifying drug delivery system (SEDDS)

Characterization of Oil, Surfactant and Co-Surfactant for Microemulsion [8-9]

Determination of Solubility in various Oil, Surfactant and Co-surfactant: Preformulation solubility analysis was done to select the vehicle in which drug is more soluble and suitable for formulation of SEDDS. The solubility of drug in various oils, surfactants and co surfactants was measured and the solvents for the study were selected based on the good solublising capacity for drug. In present study the solubility of drug was investigated in different oils like Capryol-90, soyabean, olive oil etc, surfactants and co-surfactants like Tween 80,labrasol, Cremophor RH40 and PEG 400, Propylene glycol ,Transcutol HP etc. An excess amount of drug was added into each vehicle followed by vortex mixing for 30sec (Remi mixer, Mumbai). Mixtures were shaken for 48 h at 300 C, followed by equilibrium for 24 hr. The equilibrated samples were then centrifuged at 1000 rpm for 10 min to remove the insoluble drug and clear supernatant liquid was decanted. An aliquot of the supernatant was diluted with ethanol and solubility of drug was estimated by UV spectroscopy at 255 nm.

Screening of oils and surfactant: The oils and surfactants were selected on the basis of their tendency for instant emulsification and solubility in extract. The oils selected for this investigation were, Capryol-90 and Soyabean oil. The surfactants selected were Tween 80, Labrasol and Cremophor EL. The oils and surfactant were mixed in a ratio of 1:1. Briefly, 150 mg of the surfactants were added to 150 mg of the oily phase. Each mixture, 100 mg, was then diluted with distilled water to 100 ml in a stoppered conical flask. Ease of emulsification was judged by the number of flask inversions required to yield homogenous emulsion. Emulsions were allowed to stand for 2hr and their % transmittance was evaluated at 638 nm by UV-Visible spectrophotometer using distilled water as a blank. Emulsions were furthermore observed visually for any turbidity or phase separation.

Preliminary screening of co-surfactants: The selected oily phase and surfactant were used for further screening of the different co- surfactants (Propylene glycol, PEG 400 and Labrasol) for their emulsification ability. Mixtures of 200 mg of co-surfactant, 400 mg selected surfactant, and 600 mg screened oil were prepared and evaluated in a similar fashion as described in preliminary screening of surfactants.

Formulation of Self Emulsifying Drug Delivery System[8-10]

Self Emulsifying Drug Delivery system of *Andrographic paniculata* extract was formulated by mixing oil, surfactant and co-surfactant with varying component ratio. In all the formulation amount of *Andrographic paniculata* extract was kept constant and varying ratio of oil and Surfactant and co surfactant mixture was added. The required amount of *Andrographic paniculata* extract was dissolved in selected oil at room temperature by permanent agitation and then mixture of surfactant and co-surfactant were added with gentle stirring and sonication. Then an appropriate amount of water was added to the mixture drop wise with constant stirring. Micro emulsion of *Andrographic paniculata* extracts was obtained spontaneously on stirring the mixture at ambient temperature. The various formulation ratios (AF1 to AF8) are given in Table 1. The process of self-emulsification was visually monitored for the rate of emulsification and for the appearance of the produced emulsions. The visual properties registered against the increment of the applied surfactant component in Ternary triangular diagrams. Plotting points of preferential combinations were selected according to calculation.

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Table 1: Compositions of *Andrographic paniculata* extract (SNEDDS) (1–8)

Compositions	Formulation code	Capryol-90	PEG-400	Cremophore RH 40	Labrasol
Composition 1	AF1	35 %	35 %	30 %	-
Composition 2	AF2	25 %	50 %	25 %	-
Composition 3	AF3	20 %	60 %	20 %	-
Composition 4	AF4	25 %	25 %	50 %	-
Composition 5	AF5	35 %	35 %	-	30 %
Composition 6	AF6	25 %	50 %	-	25 %
Composition 7	AF7	15 %	60 %	-	15 %
Composition 8	AF8	25 %	25 %	-	25%

Evaluation of Formulation Self Emulsifying Drug Delivery System [10-21]

Drug content: Self-emulsifying drug delivery systems formulation equivalent to 100 mg of *Andrographic paniculata* extract was taken and dissolved in small quantity of ethanol. Volume was made up to 100 ml with ethanol solution (1 mg/ml). From the above stock solution, 0.2 ml (200 µg/ml) was withdrawn and diluted up to 10 ml with ethanol (20 µg/ml). Samples were prepared in triplicate and absorbance measured at 224 nm using UV-visible spectrophotometer. ethanol was used as a reference solution.

Self emulsification assessment: SMEDDS should form stable microemulsion instantaneously in GI fluids upon administration. Efficiency of selected combination of surfactant and co-surfactant in self microemulsification was assessed by dispersing the SMEDDS in 250 mL of water with magnetic stirring at 100 rpm to create gentle turbulence that mimic in vivo condition and assessed visually.

***In-vitro* dissolution studies:** The quantitative *in-vitro* dissolution studies are carried out to assess drug release from oil phase into aqueous phase by USP type II dissolution apparatus use of 900 ml of pH 6.8 phosphate buffer solution at 75 rpm and maintain the temperature at 37°C ± 0.5°C. Aliquots of 5 ml samples were withdrawn at regular intervals of time (5, 10, 15, 30, 60 min) and volume withdrawn was replaced immediately with fresh medium. Samples taken were then analyzed by use of UV spectrophotometer at 224 nm.

Accelerated Stability Studies

The optimized formulations SEDDS were filled in the glass vial, sealed with rubber cap and crimped for storing in the stability chamber. Samples were subjected to a stability testing for six months as per ICH norms at a temperature and RH of 40°C ± 2°C/75% RH ± 5% RH respectively. The selected formulations were analyzed for the change in droplet size, zeta potential, self-emulsification capacity and drug content .

Solubility Profile

Solubility of powdered extract of *Andrographic paniculata* in various solvent are presented is in Table.2 It can be revealed from table that *Andrographic paniculata* is soluble in ethanol, thus ethanol was selected for further studies.

Table 2: Solubility Profile of *Andrographic paniculata* extract

S. No	Solvent	Solubility
1.	Distilled Water	Sparingly Soluble
2.	Methanol	Soluble
3.	Ethanol	freely Soluble
4.	Acetone	Sparingly Soluble

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5.	Chloroform	Sparingly Soluble
6.	Phosphate Buffer (5.4 pH)	Sparingly Soluble

Analytical Methodology UV-Visible Spectroscopy

The Lamda max (λmax) of *Andrographic paniculata* extract in ethanol was found to be 224 nm.

The ultraviolet spectrum of pure andrographolide, which is responsible for most of the anti-inflammatory activity, shows a maximum absorption at 223–224 nm in methanol or ethanol.

Characterization of Oil, Surfactant and Co-Surfactant Selection of Excipients

In this study, we selected Cremophor RH 40, Tween 80 and Labrasol as a surfactant. Transient negative interfacial tension and fluid interfacial film are rarely achieved by the use of single surfactant; usually, addition of a co surfactant is necessary. The presence of co surfactant decreases the bending stress of interface and allows the interfacial film sufficient flexibility to take up different curvatures required to form microemulsions over a wide range of composition.

Table 3: Solubility of *Andrographic paniculata* in Various Oil, Surfactant and Co-surfactants

S. No.	Solvent		Solubility (µg/ml) of Andrographic paniculata
1.	Oil	Olive Oil	32.1
		Capryol-90	71.4
		Soyabean Oil	41.5
2.	Surfactant	Tween 80	65.23
		Labrasol	70.43
		Cremophor RH 40	75.41
3.	Co-surfactant	Propylene Glycol	39.9
		PEG 400	58.7
		Transcutol HP	43.23

Thus, co surfactant selected for the study was PEG 400, which has an HLB value of 11-16. Surfactants and co-surfactants were selected on the basis of their emulsification efficiency and ability to solubilise *Andrographic paniculata* extract.

Drug content

The % drug content of all SEDDS formulations was found to be within the acceptable limits of drug content test. The Assay results are shown in table.

Table 4: Drug Content of SEDD formulation with *Andrographic paniculata* extract

S. No.	Formulation	Percentage of Drug contents (X ± SD)
1	AF1	96.5±1.7
2	AF2	98.6±0.5
3	AF3	98.9±0.7
4	AF4	96.8±96
5	AF5	96.6±0.9
6	AF6	98.4±0.8
7	AF7	97.3±1.3
8	AF8	93.3±1.8

SD = Standard deviation

Determination of self-emulsification time

Emulsification time is an important index for the assessment of the efficiency of emulsion formation. SEDDS should disperse completely and rapidly when subjected to aqueous dilution under mild agitation. Formulation should disperse quickly when subjected to aqueous dilution under gentle agitation of GIT due to peristaltic activity. The emulsification time of all formulations was reported in Table The lowest emulsification time 57 seconds was found in AF3 formulation and highest emulsification time 124 seconds was found in HF8 formulation .After observation it was found that the AF3 formulation forms microemulsion in a short time relatively among

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all other formulations which indicate that the AF3 was best of all prepared formulations.

Table No.6: Self Emulsification time of SEDDS formulation

S. No.	Formulation	Self Emulsification Time
1	AF1	98 ± 1.8
2	AF2	66 ± 0.4
3	AF3	57 ± 0.6
4	AF4	101 ± 2.8
5	AF5	101± 0.7
6	AF6	98 ± 5.6
7	AF7	76 ± 1.3
8	AF8	124 ± 2.4

***In-vitro* dissolution study**

In-vitro dissolution study was conducted to compare the pure extract release from the developed *Andrographic paniculata* extract SEDDS formulation. Quantitative in vitro dissolution studies are performed to assess drug-release from the oil phase to the aqueous phase by USP Type II dissolution apparatus.

The results of the in vitro dissolution studies were listed in the table and figures below. After looking at the results, it was found that, about 95.32% drug was released from *Andrographic paniculata* SEDDS AF3 formulation within 60 minutes as compared to other formulations, i.e. AF1, AF2, AF4, AF5, AF6, AF7 and AF8, which were 67.85%, 83.10%, 57.91%, 62.85%. 78.81,87.95% and 55.15% of the drug respectively. Thus, the drug release from *Andrographic paniculata* SEDDS AF3 formulation was found to be significantly higher as compared to the remaining SEDDS formulation and pure extract. It could be suggested that the SEDDS AF3 formulation resulted in the spontaneous formation of a microemulsion with smaller droplet size, which allowed a faster release rate of the drug into the aqueous phase. Thus, greater availability of dissolved *Andrographic paniculata* extract from the SEDDS AF3 formulation may lead to higher absorption and higher oral bioavailability.

The release data obtained in this study was extrapolated by zero order, first order, Higuchi, Korsmeyer-Peppas, Hixon-Crowell equations to know the mechanism of drug release from the formulation. The in vitro drug release profile of the optimized formulation AF3 was best expressed by the Higuchi equation as the plots showed the highest linearity (coefficient of determination, R2 = 0.993).

The formulations showed good linearity when plotted according to Higuchi equation. It can be inferred that the release was dependent on both motility and polymer relaxation.

Table 8: In-vitro drug release profile of SEDDS formulation

Time	SEDDS Formulation							
	HF1	HF2	HF3	HF4	HF5	HF6	HF7	HF8
5	20.63	26.85	32.85	19.25	18.81	20.81	28.4	17.85
10	38.32	41.82	46.98	30.98	32.32	37.63	40.47	29.21
15	42.23	53.84	58.75	40.45	43.22	49.76	50.19	39.36
30	54.83	60.68	74.18	46.40	49.87	58.85	66.55	49.44
45	61.25	71.45	89.81	53.47	58.81	70.43	77.32	50.47
60	67.85	83.10	95.32	57.91	62.85	78.81	87.95	55.15

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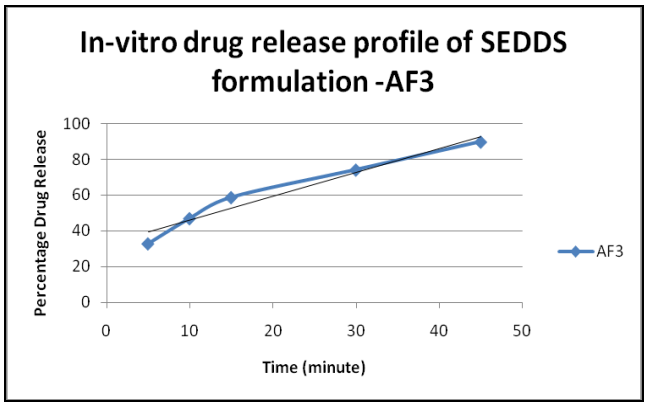

Figure 1; Percentage drug release Study of optimized formulation

Stability Studies

Samples from stability chamber were withdrawn at regular intervals and evaluated for self emulsification efficiency, droplet size and zeta potential measurements. Results were represented in Table. There was no significant change in the droplet size, zeta potential and self-emulsification capacity. Clear dispersion with closer droplet size with initial samples indicates the stability of SMEDDS.

Table 9: Stability studies of Formulation

Formulation Code	Self emulsification time (min)	Drug contents
HF3	65 ±0.4	98.12

References

1. Gursoy RN, Benita S. Self-Emulsifying Drug Delivery System (SEDDS) for Improved Oral Delivery of Lipophilic Drugs. Biomed & Pharm 2004; 58:173-82.
2. Kaukonen AM, Boyd BJ, Porter CJ, Charman WN. Drug solubilization behavior during in vitro digestion of simple triglyceride lipid solution formulations. Pharm Res 2004; 21:245-53.
3. Kumar A, Sharma S, Kamble R. Self Emulsifying Drug Delivery System (SEDDS): Future Aspects. Int J Pharm Pharm Sci 2010; 2(4):7-13.
4. Dabros T. Emulsification through area contraction. J Colloids Interface Sci 1999; 210:222-30.
5. Reiss H. Entropy induced dispersion of bulk liquids. J. Colloid Interface Sci 1975; 53:61-70.
6. Wakerly MG, Pouton CW, Meakin BJ. Evaluation of the self-emulsifying performance of a non-ionic surfactant-vegetable oil mixture. J Pharm Pharmacol 1997; 39:6.
7. Charman WN, Stella VJ. Transport of lipophilic molecules by the intestinal lymphatic system. Adv Drug Del Rev 1991; 7:1-14.
8. Gupta AK, Mishra DK. Preparation and evaluation of selfemulsifying drug delivery system of anti-hypersensitive drug valsartan. Int J Pharm Life Sci 2011;2: 633-639.
9. Tejinder kaur marwaha et all.,"formulation design and evaluation of anti-inflammatory activity of commiphora mukul loaded emulgel", Journal of research and education in Indian medicine, April-June 2014; Vol. XX (2): 75-87
10. Gupta A.K., Mishra D.K. and Mahajan S.C.Preparation And In-Vitro Evaluation of Self Emulsifying Drug Delivery System of Antihypertensive Drug Valsartan. Int. J. of Pharm. & Life Sci. (IJPLS), Vol. 2, Issue 3: March: 2011, 633-639
11. Chopade VV, Chaudhari PD. Development and evaluation of self-emulsifying drug delivery system for lornoxicam. Int J Res Dev Pharm Life Sci 2013;2:531-7.
12. Patel PA, Chaulang GM, Akolkotkar A, Mutha SS, Hardikar SR, Bhosale AV. Self-emulsifying drug delivery system: A review research. J Pharm Technol 2008;1:54-68.
13. Sapraa K, Saprab A, Singha SK, Kakkarb S. Self-emulsifying drug delivery system: A tool in solubility enhancement of poorly soluble drugs. Indo Glob J Pharm Sci 2012;2:313-32.

Journal of Chemical Health Risks

www.jchr.org

JCHR (2026) 16(2), 238-244 | ISSN:2251-6727

14. Harshal DM, Shaikh T, Baviskar D, Rajendra DW. Design and development of solid self-micro-emulsifying drug delivery system (smedds) of fenofibrate. Int J Pharm Pharm Sci 2011;3 Suppl 4: 163-166.

15. Pandya D, Patel P, Patel S. Formulation & development of selfmicro emulsifying drug delivery systems of amiodarone HCl for dissolution enhancement. Discov Pharm 2013;5:6-12.

16. Tran, P.; Park, J.-S. Recent trends of self-emulsifying drug delivery system for enhancing the oral bioavailability of poorly water-soluble drugs. *J. Pharm. Invest.* **2021**, *51*, 439– 463,

17. Kabil, M. F.; Dena, A.S.A.; El-Sherbiny, I. M. *Ticagrelor, in Profiles of Drug Substances, Excipients and Related Methodology*; Elsevier, 2022; pp 91– 111.

18. Khalid, K. W.; Abd Alhammid, S. N. Preparation and in-vivo Evaluation of Ticagrelor Oral Liquid Self nano-emulsion. *J. Pharm. Negat. Results* **2022**, *13* (3), 274.

19. Ashfaq, M.; Shah, S.; Rasul, A.; Hanif, M.; Khan, H. U.; Khames, A.; Abdelgawad, M. A.; Ghoneim, M. M.; Ali, M. Y.; Abourehab, M. A.Enhancement of the solubility and bioavailability of pitavastatin through a self-nanoemulsifying drug delivery system (SNEDDS). *Pharmaceutics* **2022**, *14* (3), 482.

20. Shafiq, S.; Shakeel, F.; Talegaonkar, S.; Ahmad, F. J.; Khar, R. K.; Ali, M. Development and bioavailability assessment of ramipril nanoemulsion formulation. *Eur. J. Pharm. Biopharm.* **2007**, *66* (2), 227– 243.

21. Jianxian, C.; Saleem, K.; Ijaz, M.; Ur-Rehman, M.; Murtaza, G.; Asim, M. H. Development and in vitro evaluation of gastro-protective aceclofenac-loaded self-emulsifying drug delivery system. *Int. J. Nanomed.* **2020**, *15*, 5217– 5226.