International Journal of Environmental Sciences
ISSN: 2229-7359
Vol. 11 No. 21s, 2025
https://theaspd.com/index.php

Formulation and Evaluation of Self-Emulsifying Drug Delivery System of Cassia Tora

Bhojraj Tanbaji Satpute[1], Dr. Nidhi Bais[2]
[1]Research Scholar, Institute of Pharmacy, Oriental University, Indore, M.P.
[2]Associate Professor, Institute of Pharmacy, Oriental University, Indore, M.P
Corresponding Author: Bhojraj Tanbaji Satpute, bhojraj.satpute75@gmail.com

Abstract
Aim: *The goal of this study was to create a self-emulsifying Cassia tora drug delivery system, which would enhance its dissolution efficiencies, solubility, and bioavailability.*
Materials and Methods: *Cassia tora's solubility in various types of cosurfactants, oils, and surfactants was determined. A pseudoternary phase diagram was developed using Cremophor EL, Gelucire 44/14 and PEG 400 to identify the optimal region for emulsification. Other factors such as the emulsification time and drug content were also evaluated.*
Results and Discussion: *The optimized formulation of Cassia tora showed various characteristics, such as its small particle size, high solubility, and good optical clarity. In vitro release was also improved with the help of this formulation. Data importing was performed using HPTLC.* ***Conclusion:*** *The study revealed that SEDDS could be a promising method of delivering poorly soluble drugs orally.*

INTRODUCTION

The oral route is the most convenient and simplest method of non-invasive treatment. However, it can be problematic when it comes to the solubility of drugs. The preferred method is the delivery system that involves the self-emulsification of drugs. This is a major component of the treatment of various diseases. The oral delivery of around 40% of the drugs is affected by their high lipophilicity. This issue can cause low bioavailability, variability across subjects, and insufficient dose balance. About 40% of new medications have a low solubility. [1-3]

Class-II drugs are those that have high permeability and low solubility according to the BCS.The process of self-emulsifying drugs involves the use of isotropic mixtures composed of various natural or synthetic oils, as well as liquid or solid surfactants or one or more hydrophilic substances. These systems can create fine oil in water by diluting or gently agitating it.Self-emulsification techniques allow drugs to easily reach the GI tract. The digestive and stomach movements facilitate the process. Once the drug is solubilized, it can be absorbed through the lymphatic system. Studies have shown that SEDDS can enhance oral absorption of various drugs by facilitating transcellular transport, opening tight junctions for paracellular transport, and raising intracellular concentrations. The use of SEDDS techniques for the oral delivery of drugs with low water-soluble components is a promising strategy for addressing this issue. The dissolution of the hydrophilic substance in a suitable solvent prior to the formulation's filling in the oral dosage form allows for the desired effect.[4-6]Cassia tora is a type of seed that can be used as a substitute for coffee. Studies have been conducted on its utilization in various food products. Cassia tora powder is a popular ingredient in pet food.

Cassia tora is commonly used in organic farms in India as a natural pesticide. It is known to have various active substances, such as emodin, chrysophenol, and rhein. It has been reported that this plant has antimutagenic properties. This substance, which is an Ayurvedic preparation known as Dadhughnavati, is one of the most effective antifungal agents. Cassia tora seeds and leaves are known to have various anti-inflammatory, anti-oxidant, and laxative properties. In addition, they can help treat various diseases, such as ringworm, gastrointestinal distress, and constipation. In tropical Africa, the seeds and leaves can be used for treating fever, oedema, and roundworm infection. The seeds of Cassia tora contain various antinutritional compounds, such as trypsin inhibitors and total free phenolics tannins. These factors do not have a significant nutritional value if the seeds are processed properly. Cassia tora is full of minerals and proteins, and it also has antinutritional properties.

Various traditional medicines, such as those used by Chinese, Unani, Siddha, and Ayurveda, have been known to utilize plants as effective remedies. Since they are relatively inexpensive and nontoxic, the demand for such products has been growing.SEDDS can help prevent drugs from going through the hepatic first-pass process, which occurs when the liver metabolizes them before they reach the systemic circulation. This process can lead to poor drug absorption and a reduction in their bioavailability. The advantages of utilizing SEDDS are numerous, such as the oral bioavailability of drugs that are or highly permeable[7].

MATERIAL AND METHODS

Selection of Plant and Excipients

Fresh leaves of Cassia tora were collected from India.

Procurement of Plant and Raw Materials

The leaves of the C. tora Linn tree were taken from the Bhandara Districtof Maharashtra, which was authenticated by Professor N.M. Dongarwar, Botany Department, Nagpur University and a voucher specimen has been deposited at the herbarium of the Department of Botany to the Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur, Maharashtra state. The leaves were separated from the twigs, cleaned, dried, and sized-reduced to a coarse powder for analysis. Fresh leaves were utilized for histological studies.(Show in figure.1)

Figure.1. Cassis tora plant

Morphological Study of Crude Drugs and Preliminary Phytochemical Screening

A detailed morphological study of the crude leaves of Cassia tora was conducted, focusing on their structural characteristics and physical appearance [8]. The leaves are typically ovate, smooth, and dark green with prominent venation patterns, aiding in their identification.

Preliminary Phytochemical Screening

The preliminary phytochemical screening of Cassia tora leaves revealed the presence of various bioactive compounds, predominantly polyphenols. This observation encouraged further evaluation of their antioxidant and antiproliferative potential.

Identified Phytochemicals

- Emodin and Kaempferol-2-diglucoside were reported in the leaves, both known for their significant pharmacological activities.
- Chrysophenol, aloe-emodin, and rhein were identified, which are anthraquinones with notable antioxidant properties.
- Glucose, 1-stachydnine, amino acids, fatty acids, and d-mannitol were also detected, contributing to the plant's nutritional and medicinal value.
- β-sitosterol and myricyl alcohol were identified as major phytosterols with potential cholesterol-lowering effects.
- Trigonelline and choline were present, known for their neuroprotective and metabolicregulatory properties.

Table 1: Microscopic study

Size	2.0-5.0cm
Shape	Lanceolate
Margin	Entire
Venation	Pinnate veins, anastomosing towards the margin
Apex	Acute
Base	Asymmetrical
Surface	Pubescent with press markings
Texture	firm, flexible
Colour	pale green yellowish green
Taste	mucilaginous bitter
Odour	faint
Attachment	Petiolate
Phyllotaxy	Opposite
General Appearance	Entire and less broken

Morphological study of crude drugs

The presence of various polyphenols in the leaves has prompted researchers to analyze its antiproliferative and antioxidant properties. They also reported the presence of various other nutrients such as acetylsalicylic acid, glucose, and amino acids. [9]

Known for their medicinal properties, the leaves of the plant can contain various types of sennosides. The percentage of these in the C. tora leaves was 0.14. They also contain Kaempferol-3-diglucoside and Ononitol monohydrate, which are potential hepatoprotective substances.

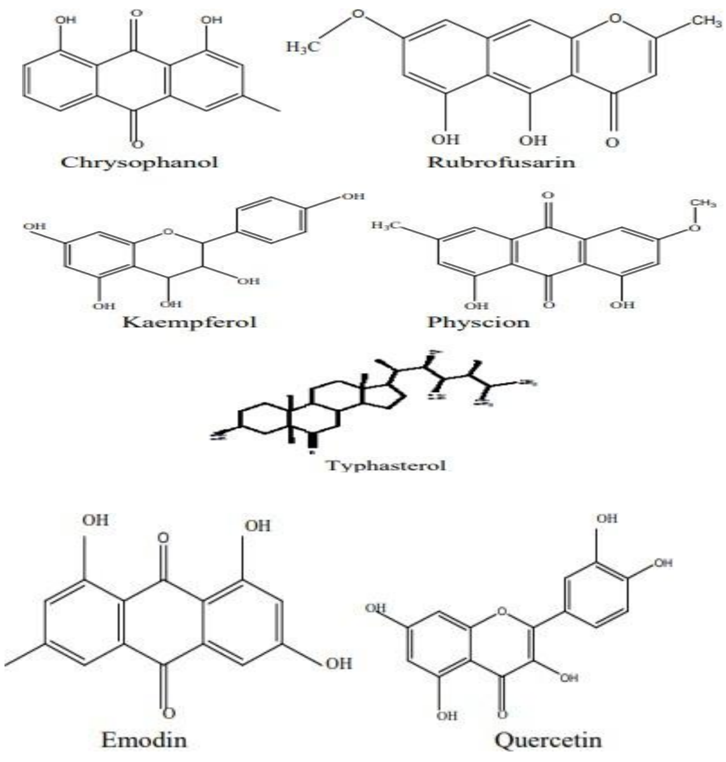


Figure.2. Chemical structures of some phytoconstituents of Cassia tora

Preformulation Studies

The goal of this test was to determine the solubility of cassia tora extract in various types of cosurfactants, oils, and surfactants. A couple of mL of each of these substances was placed in cap tubes containing 500mg of this extract. [10-12]. A vortex mixer was used to mix the ingredients after about 5 minutes in a bath. They were then shaken using a thermal shaker. The mixtures were then evenly distributed at room temperature for 24 hours. At a rate of 3000 rpm, the supernatant was centrifuged for around 10 minutes. It was then filtered through a membrane filter, and its concentration was measured using the HPLC method.

Preparation of SEDDS

The optimal ratios of S/CoS and OA were selected based on the phase diagrams. The SEDDS formulations were then prepared by adding OA to the mixtures after dissolving cassia tora. Different batches were then designed to study the effects of the different formulation variables. Each batch had varying amounts of OA and COS, and the formulas were stored in a humidified environment for further study.

Invitro Characterization of Optimized SEDDS

A dissolution test was conducted by Electrolab India to evaluate the emulsification process of SEDDS formulations. The solution containing 500 ml of this formulation was added at a speed of 37 degrees Celsius. A gentle agitation was then performed using a paddle.

The time taken for the emulsifying process was recorded manually. Studies on pseudo ternary phase diagrams revealed that the 4:1 ratio of surfactant showed large micro-emulsion regions. It was selected for the formulation of SEDDS[13-15].

The water consuming ratios of the first two levels of the cassia tora surface enhanced design standard (SEDDS) are selected and evaluated using a 22-factorial approach. The results of the optimization and formulation process were shown in Table 2.

Table. 2. Optimization and formulation of cassia tora

Component	F1	F2	F3	F4
Cassia tora extract	100			
S mixture(%)	Low (47.2)	High (54)	Low(47.2)	High (54)
Oil (%)	Low (23)	High (32.1)	High (31.1)	Low (23)

Table. 3. Factorial designs of cassia tora SEDDS for 100mg of cassia tora: Independent (X) and Dependent variables (Y).

Independent Variables				Dependent Variables		
Batch (SES)	X1	X2	Y1	Y2	Y3	Y4
	OA mg	Surfactant Mixture (Tween 80– PEG 400)mg	ATVrelease(%) after10min mg	Microemulsion Droplet Size µm	%Trans-mittance	Emulsification Time min
1	400	300	66.52	20.52	93.94	2.15
2	400	500	80.11	11.33	96.76	1.82

3	400	700	94.52	13.41	96.73	1.41
4	200	300	72.52	15.50	97.31	2.15
5	200	500	88.54	8.80	98.92	1.7
6	200	700	95.78	8.432	99.19	1.32
7	600	300	61.00	27.69	93.50	2.23
8	600	500	72.12	26.91	93.47	1.9
9	600	700	89.44	17.42	95.31	1.35
SES = self-emulsifying system.						

HPTLC Profile (High Performance Thin Layer Chromatography).

Sample Preparation

SEDDS formulation Cassia Tora and std drug dissolved with methanolobtained were evaporated under reduced pressure using roto vacuum evaporator. Eachsample residue was re-dissolved in 1ml of chromatographic grade chloroform, ethyl acetate and 90% ethanol, which was used for sample application on pre-coated silica gel 60F254 aluminium sheets.

Developing Solvent System

A number of solvent systems were tried, for extract, but the satisfactory resolution was obtained in the solvent n Hexane: Ethyl acetate (3.5:1.5).

Sample Application

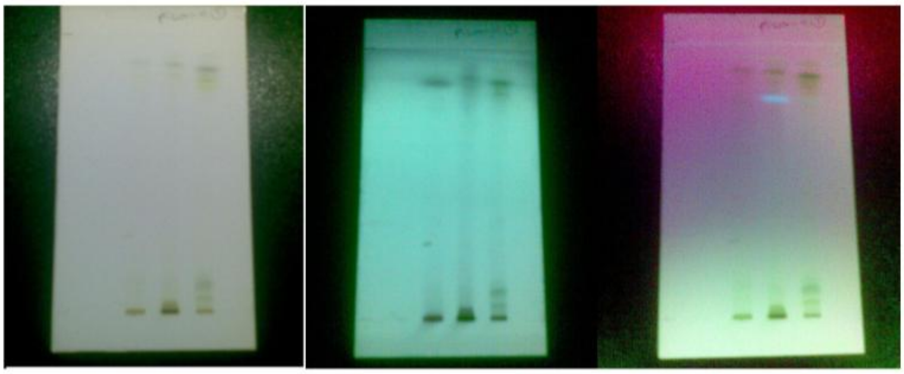
Application of bands of each extract was carried out (4mm in length and 1ul in concentration for SEDD formulation of Cassia Tora and Moringa Oleifera and 90% methanolic extracts) using spray technique. Sample were applied in duplicate on pre- coated silica gel 60F254 aluminum sheets (5 x 10 cm) with the help of Linomat 5 applicator attached to CAMAG HPTLC system, which was programmed through WIN CATS software.

Development of Chromatogram

After the application of sample, the chromatogram was developed in Twin trough glass chamber 10x 10 cm saturated with solvent n-Hexane: ethyl acetate (3.5:1.5) for 15 minutes.

Detection of Spots

The air-dried plates were viewed in ultraviolet radiation to mid-day light (Figure 3). The chromatograms were scanned by densitometer at 420 nm after spraying with anisaldehyde sulphuric acid. The R f values and finger print data were recorded by WIN CATS software. HPTLC plate Visible light 254nm 366nm



HPTLC plate Seen at Visible light **HPTLC plate seen at 254nm** **HPTLC plate seen at 366nm**

Figure. 3. HPTLC profile of SEED formulation of Cassia Tora

Track 1: SEDD formulation of Cassia Tora
Track 2: Plant extract
Track 3: Std drug glibenclamide
The results from HPTLC finger print scanned at wavelength 420 nm for SEDD formulation ofCassia Tora showed six polyvalent phytoconstituents and corresponding ascendingorder of Rf values start from 0.04 to 0.94 in which highest concentration of the phytoconstituents wasfound to be 39.00% and its corresponding R f value was found to be 0.04 respectively and was recorded in Table 4. The corresponding HPTLC chromatogram was presented in Figure 4.

Table. 4. Rf Values for SEDD formulation of Cassia tora

Peak	Start Position	Start Height	Max Position	Max Height	Max %	End Position	End Height	Area	Area %
1	0.01Rf	163AU	0.01 Rf	185.5 AU	39.00 %	0.04Rf	39.8 AU	3033.3 AU	34.52 %
2	0.07Rf	0.5AU	0.11 Rf	42.5AU	8.94%	0.14Rf	1.00 AU	1213.8 AU	13.81 %
3	0.76Rf	2.4AU	0.79 Rf	46.1AU	9.69%	0.81Rf	10.8AU	954.7AU	10.87 %
4	0.84Rf	4.2AU	0.86 Rf	29.5AU	6.20%	0.88Rf	16.7AU	571.4AU	6.50 %
5	0.88Rf	17.2AU	0.90 Rf	161.9 AU	34.03 %	0.92Rf	7.5AU	2860.6 AU	32.56 %
6	0.92Rf	8.0 AU	0.93Rf	10.2AU	2.15%	0.94Rf	6.0 AU	152.7AU	1.74 %

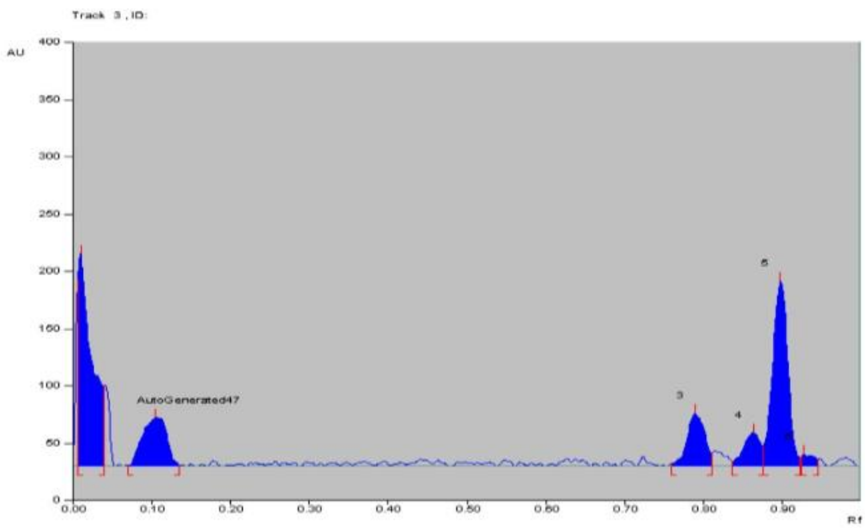


Figure. 4. Chromatogram of SEDD formulation of Cassia tora.

Estimation of Zeta Potential

The ZP measurement was carried out to analyze the charge and stability of polymers. The data collected by the measurement revealed that the mucilage in water had a ZP of 18.05mV, while in 0.1N NaCl, it was 5.15mV[16].

Particle Size Analysis.

The particle size of mucilages obtained using the Zetatrac analyzer was determined to be in fine particle size ranging from 500 to 551 nm.

Spectroscopic Characterization of Optical Clarity

The distilled water used for diluting each formulation of cassia tora equivalent to 10 mg was 500 ml. Absorbance values of the different emulsions were measured by an ultraviolet spectrophotometer at 400 nm.

Fourier transform infrared studies

The objective of the FT-IR studies is to characterize the interactions between the drug and other excipients. We are performing the studies on the best and pure formulations to see how they interact with each other [17-27].

Figures 5 and 6 show the best SEDDS formulations. The peak at 758.787 cm1 is a characteristic of the aromatic group's C-H bending. The peak at 1289 cm1 is a result of C=O stretching in alcohols. On the other hand, the peak at 1461 cm1 is a typical of C=C stretching in aromatic groups.

The peaks at 1585 and 1643 cm1 were characterized by C=N stretching and N=N stretching. The 3184 cm1 peak was also highlighted by C-H-Alkene group in the molecule. No interaction was detected between the NVP and the excipients after the FT-IR studies on the best and purest formulations.

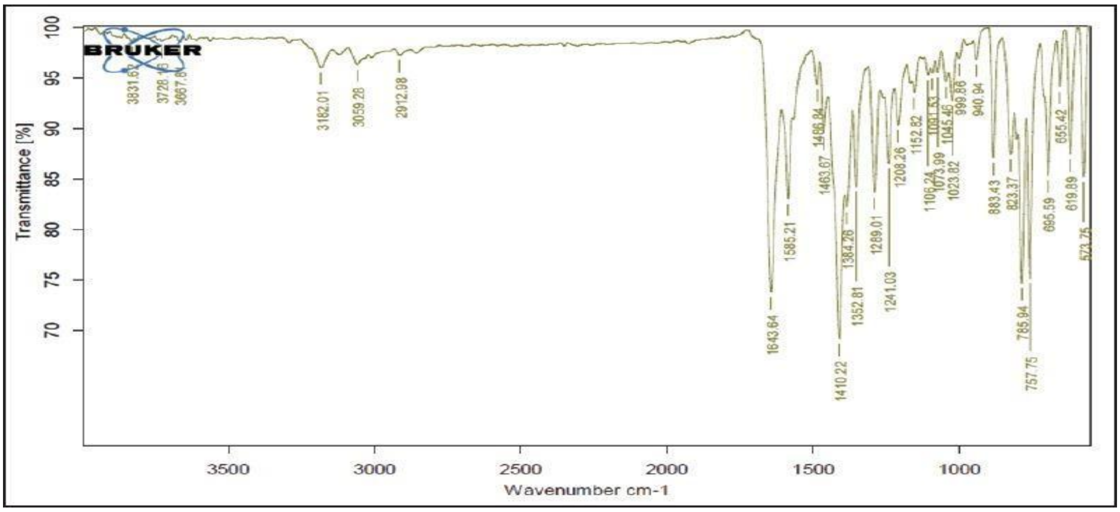


Figure. 5. Fourier transform infrared graph of cassia Tora pure drug.

Powder X-Ray Diffraction Pattern.

Mucilage patterns were computed using an X-ray diffractometer. Experiments were performed at 25 degrees Celsius. The measurements were carried out under different conditions, such as voltage 40 kv, current 30mA, and a 2 x angle with a scan step time of 10.33 s.

Differential Scanning Calorimetry.

The use of DSC has made it possible to monitor the chemical and physical changes that happen in a given gum during its thermal processing. These methods yield curve that are unique to a specific type of gum. For instance, after analyzing mucilage, the transition temperature of the glass was found to be 138 degrees Celsius.

The intense peak that was observed in the DSC thermograms was an endothermic transition. It occurred at around 200 degrees Celsius.

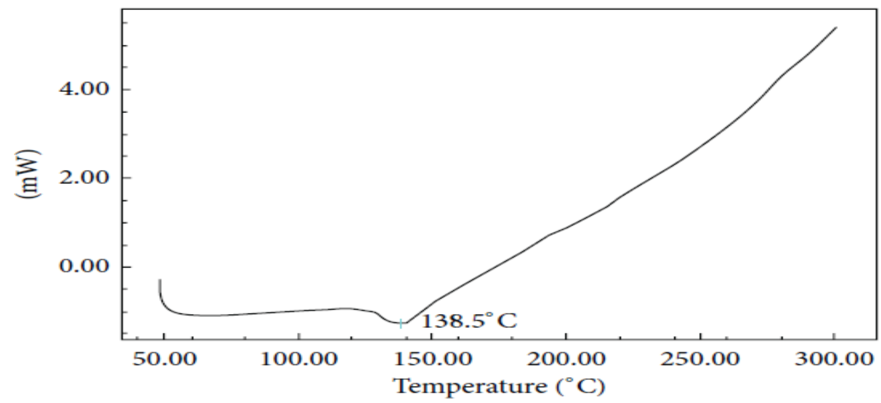


Figure. 6. Differential scanning calorimetry (DSC) characterization of cassia tora Using DSC analyzer.

Scanning Electron Microscopy

The SEM of cassia tora is shown in Figure 7 with different magnifications. Its microscopic images show that it is a material that is amorphous, and its fibrous nature makes it look like various irregular shapes.

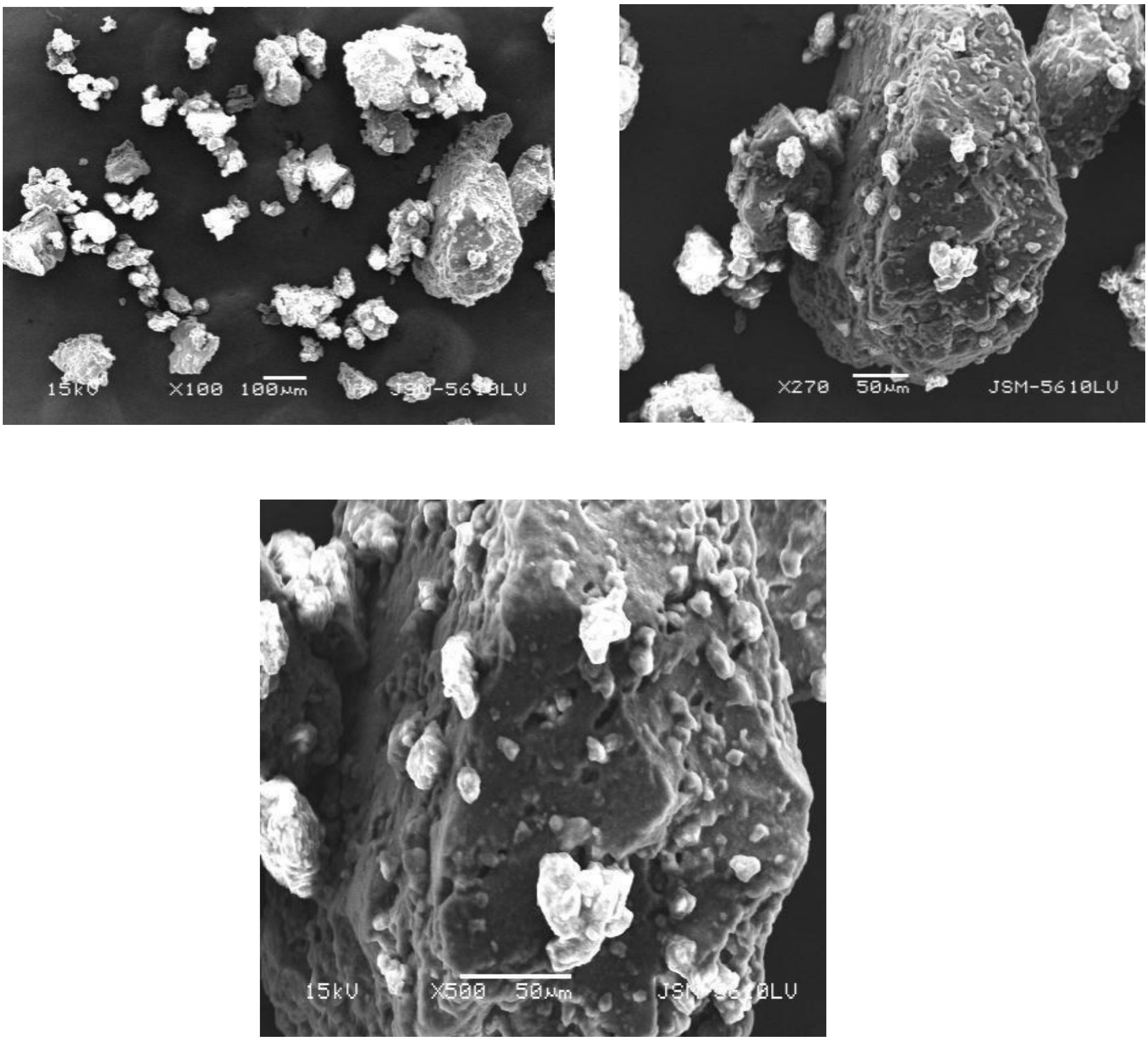


Figure. 7. Scanning electron microscopy of cassia tora at different magnifications using SEM.

InVitro Dissolution Studies

SEDDS dissolution studies were carried out using the electrolab's device II at a speed of 50 revolutions per minute. The samples were then placed in gelatin capsules and subjected to a dissolution medium that was distilled water. The temperature and volume of the medium at which the dissolution took place were 37 degrees Celsius and 1000 mL, respectively.

Stability Study

The optimized cassia tora surface enhanced degradation system (SEDDS) was subjected to a stability test in a controlled environment for three months at 40 degrees Celsius/75% relative humidity. The optimized SEDDS was placed in a stability chamber at Thermolab India for three months. The samples were periodically withdrawn for evaluation.

RSM method

The collected data was analyzed and compared using various regression techniques. The results of the study were then fitted in equations 1. The main variables that were considered were the amo2U2nt2 of the OA and S/CoS mixtures, as well as the self-Emulsification Time and droplets size.

Table. 5. Solubility of cassiatora in different excipients

Excipient	Solubility (mg/mL)	Excipient	Solubility (mg/mL)
Arachis Oil	8.8 ±3.42	Capmul PG8	18.32 ±4.44
Soybean Oil	8.9±5.13	Cremophor RH 40	19.43±6.17
Castor Oil	9.2 ±3.10	Cremophor RH 60	21.34±3.85
Oleic Acid	49.23 ± 2.93	Cremophor EL	15.25 ± 4.02
Cremophor CO 40	11.14±5.41	Glycerol	5.91 ±5.11
Cremophor CO 60	13.54±2.91	Tween 20	32.85±6.69
Water (pH 2.1)	0.02 ± 1.61	Tween 80	38.32±3.41
Water (pH 6.0)	1.21 ± 3.04	PEG 400	40,11 ±5.7
mean ± SD			

CONCLUSIONS

The formulations of SEDDS were then developed based on the various miscibility zones found in the pseudo ternary phase diagrams. A study comparing the optimized and commercial versions of Cassia tora's tablets was performed. The results indicated that the optimized versions resulted in a significantly higher percentage of Cassia tora's drug release. The selected components were chosen based on their solubility in water. The results of chemical and physical compatibility tests revealed that the SEDDS components were well-suited for their use. Cassia tora had a solubility of around 1.0 mg/100 ml, while Cremophor CO 60 4/14 had a similar amount. This mixture forms a stable emulsion when combined with water. The various concentration ranges of co- and oil-based surfactants and their mixtures are showing strong potential for optimizing their applications. Studies on stability have shown that the optimized compounds can be highly stable.

REFERENCE

1. Midon GL, Lennernäs H, Shah VP, Crison JR. (1995). A theoretical basis for a biopharmaceutic drug classification: the correlation of in vitro drug product dissolution and in vivo bioavailability. Pharm Res 12:413–20.
2. Badadhe S, Dalavi N. (2022). Review on self nano emulsifying drug delivery system. Sys Rev Pharm 13:63–8.
3. Balakrishnan P, Lee B-J, Oh DH, et al. (2009). Enhanced oral bioavailability of dexibuprofen by a novel solid self-emulsifying drug delivery system (SEDDS). Eur J Pharm Biopharm 72:539–45.
4. Basha SP, Rao KP, Vedantham C. (2013). A brief introduction to methods of preparation, applications and characterization of nanoemulsion drug delivery systems. Indian J Res Pharm Biotechnol 1:25.
5. Betageri GV. (2019). Self-emulsifying drug delivery systems and their marketed products: a review. Asian J Pharm 13:73–84.
6. Bhattacharya S, Prajapati BG. (2015). Formulation approach of self emulsifying drug delivery system. Int J Pharm Formulat Anal 6:1–6
7. Bhupinder M, Roy G, Bajwa B, Sandeep K. (2013). Self emulsified drug delivery system for the enhancement of oral bioavailability of poorly water soluble drugs. Int J Adv Pharm Biol Chem 2:427–36.
8. Cherniakov I, Domb AJ, Hoffman A. (2015). Self-nano-emulsifying drug delivery systems: an update of the biopharmaceutical aspects. Expert Opin Drug Deliv 12(7):1121–33.
9. Buss N, Snell P, Bock J, et al. (2001). Saquinavir and ritonavir pharmacokinetics following combined ritonavir and saquinavir (soft gelatin capsules) administration. Br J Clin Pharmacol 52:255–64.
10. Caliph SM, Charman WN, Porter CJ. (2000). Effect of short-, medium-, and long-chain fatty acid-based vehicles on the absolute oral bioavailability and intestinal lymphatic transport of halofantrine and assessment of mass balance in lymph-cannulated and non-cannulated rats. J Pharm Sci 89:1073–84
11. Charman SA, Charman WN, Rogge MC, et al. (1992). Self-emulsifying drug delivery systems: formulation and biopharmaceutic evaluation of an investigational lipophilic compound. Pharm Res 9:87–93.
12. Lohar D.L., Chawan D.D. and Garg S.P., Phytochemical studies on Cassia species of Indian Arid Zone" Current Science, 1975, 44(2), 67 Hooker, J.D., the Flora of British India, Vol.II, L.Reeve and Co., England, 1879, p.26.
13. Kirtikar, K.R. and Basu, B.D., Indian Medicinal Plants, Vol II, Periodical Experts D- 42, Vivek Vihar Delhi, 1975, pg.877. Jain, S.K., Medicinal Plants, National Book Trust, New Delhi., 1968, p.37.

14. Maitya, T.K., Mandal, S.C., Mukherjee, P.K., Saha, K., Dass, J., Saha, B.P and Pal, M., Evaluation of hepatoprotective potential of Cassia tora leaf extract, Nat. Prod. Sci., 1997, 3,122. 10.
15. Maitya T.K., Mandal S.C., Saha B.P. and Pal M., Evaluation of hepatoprotective potential of Cassia tora leaf extract, Nat. Prod. Sci, 1998, 4(4), 226. 11.
16. Asolkar, L.V., Kakkar, K.K., and Chakre, O.J., Second supplement to glossary of Indian medicinal Plants, PID, CSIR, New Delhi, 1992, pg.180-181. 12.
17. Maitya T.K., Mandal S.C, Saha B.P. and Pal M., Studies on some Pharmacognostic profile of Cassia tora Linn, Ancient science of Life, 1999, XIX (3and4), 113-117.
18. Devhare, L. D., & Gokhale, N. (2021). Acid neutralizing capacity and antimicrobial potential of selected solvent extract from various indigenous plants. Journal of Advanced Scientific Research, 12(04), 175-179
19. Uplanchiwar, V. P., Raut, S. Y., & Devhare, L. D. (2021). Pharmacological assessment of antiulcer activity of gloriosa superba linn tubers in experimentally induced gastric ulcers. Journal of medical pharmaceutical and allied science, 10(3), 2852-2856.
20. Devhare, L. D., & Gokhale, N. (2022). Antioxidant and Antiulcer property of different solvent extracts of Cassia tora Linn. Research journal of pharmacy and technology, 15(3), 1109-1113.
21. Devhare, L. D., & Gokhale, N. (2023). A brief review on: phytochemical and antiulcer properties of plants (fabaceae family) used by tribal people of gadchiroli maharashtra. International journal of pharmaceutical sciences and research, 14(4), 1572-1593.
22. Devhare, L. D., & Gokhale, N. (2023). In silico anti-ulcerative activity evaluation of some bioactive compound from Cassia tora and Butea monosperma through moleculer docking approach. International journal of pharmaceutical sciences and research, 14(2), 1000-08.
23. Suruse, P. B., Jadhav, B. A., Barde, L. G., Devhare, L. D., Singh, S., Minj, K. H., & Suman, A. (2023). Exploring the potential of Aerva Lanata extract in a herbal ointment for fungal infection treatment. Journal of Survey in Fisheries Sciences, 10(1), 1922-1932.
24. Bodhankar, S. S., Devhare, L. D., Meshram, A. S., Moharkar, D. W., & Badwaik, C. B. (2023). Formulation and in vitro evaluation of dental gel containing ethanglic extract of Mimosa pudica. European Chemical Bulletin, 12(5), 1293-1299.
25. Shende, S. M., Bhandare, P., & Devhare, L. (2023). In-vitro: micropropagation of mint and investigate the antibacterial activity of mint extract. Eur. Chem. Bull, 12(5), 780-784.
26. Singh, S., Minj, K. H., Devhare, L. D., Uppalwar, S. V., Anand, S., Suman, A., & Devhare, D. L. (2023). An update on morphology, mechanism, lethality, and management of dhatura poisoning. Eur. Chem. Bull, 12(5), 3418-3426.
27. Devhare, L., & Prasad, C. (2024). Prophylactic and curative activity of Withania somnifera on experimentally induced calcium oxalate nephrolithiasis. Journal of medical pharmaceutical and allied sciences, 13(4), 6687-6695.