World Journal of Pharmaceutical Science and Research
www.wjpsronline.com
Research Article
ISSN: 2583-6579
SJIF Impact Factor: 5.111
Year - 2025
Volume: 4; Issue: 1
Page: 885-897

DEVELOPMENT OF AYURVEDIC BASED SOLANUM *TRILOBATUM PEDIATRIC* TABLET FOR RESPIRATORY DISORDER

Dr. V. Kamalakkannan*[1], Prof. Dr. B. Sangameswaran[2], S. Surya[3], D. Thavasidharan[4] and B. Udhayakumar[5]

[1]Professor, Department of Pharmaceutics, SSM College of Pharmacy, Chinniyampalayam, Erode, Tamil Nadu, India.
[2]Principal and HOD, Department of Pharmacognosy, SSM College of Pharmacy, Chinniyampalayam, Erode, Tamil Nadu, India.
[3,4,5]Under Graduate, Department of Pharmceutics, SSM College of Pharmacy, Chinniyampalayam, Erode, Tamil Nadu, India.

Article Received: 17 January 2025 | | ***Article Revised: 06 February 2025*** | | ***Article Accepted: 28 February 2025***

***Corresponding Author: Dr. V. Kamalakkannan**
IVMs, Krishnarao Bhegade Institute of Pharmaceutical Education and Research, Talegaon Dabhade Pune, Maharashtra-410507.
DOI: https://doi.org/10.5281/zenodo.14965928

How to cite this Article: Dr. V. Kamalakkannan, Prof. Dr. B. Sangameswaran, S. Surya, D. Thavasidharan and B. Udhayakumar (2025). DEVELOPMENT OF AYURVEDIC BASED SOLANUM *TRILOBATUM PEDIATRIC* TABLET FOR RESPIRATORY DISORDER. World Journal of Pharmaceutical Science and Research, 4(1), 885-897. https://doi.org/10.5281/zenodo.14965928

ABSTRACT

Ayurvedic Solanum trilobatum tablets for respiratory and inflammatory diseases: Formulation and optimization this study reports the formulation and optimization of Solanum trilobatum tablets, a traditional herbal medicine used in respiratory and inflammatory conditions. Powder characterization-Preformulation studies, tablet compression and dissolution testing were carried out to achieve desirable properties of the optimized formulation ST1. The optimized formulation ST1showed desirable properties such as hardness, friability and disintegration time. Dissolution studies revealed release of Solanum Trilobatum extract which enhances the therapeutic efficacy. The developed tablets are a promising alternative to synthetic drugs for paediatric respiratory health with further studies on long-term efficacy and safety.

KEYWORDS: Solanum trilobatum, Ayurvedic medicine, paediatric tablets, respiratory disorders, herbal formulation, dissolution studies, natural therapeutics.

INTRODUCTION

Oral drug delivery is the most preferred and convenient option as the oral route provides maximum active surface are among all drug delivery system for administration of various drugs. The attractiveness of these dosage forms is due to awareness to toxicity and ineffectiveness of drugs when administered by oral conventional method in the form of

tablets and capsules. Usually conventional dosage form produces wide range of fluctuation in drug concentration in the blood stream and tissues with consequent undesirable toxicity and poor efficiency.[1] The basic principle of ayurvedic treatment comprises of two essential parts. There are to prevent the cause of disease and to make the patient more aware about the cause of the disease. Ayurveda treats a patient as a whole and not the disease alone. This system of medicine emphasizes the uniqueness of each person with regard to bio-identity, socio-economical status, bio-chemical and physiological conditions, which may lead to a particular type of illness. Ayurveda needs further exploration with modern scientific approaches for addressing various healthcare issues. Ayurvedic system adopts a holistic approach towards healthcare by balancing the physical, mental and spiritual functions of the human body. Science of Ayurveda is unique as it provides opportunity to make a healthy, harmonious and long life.[2] Over the past few decades, research on Ayurveda through various endeavours has given rise to interdisciplinary research programmes employing several disciplines in this field. Several lead molecules, ready to use products and processes are emerging. It is quite popular among people due to their practical benefits, traditional beliefs, economical advantage and easy access.[3] The development of Ayurvedic medicine is gaining momentum in keeping with the perspectives of safety, stability, efficacy and quality for betterment of human health. Medicinal plants serve as most valuable source for remedy of many diseases. The increasing search for therapeutic agents derived from plant species is justified by the emergence of new diseases. Bioactive compounds from different medicinal plants have a major role in the management and improvement of human health.[4]

Ayurvedic medicines are used as raw, crude materials, extracts and preparations for therapeutic purposes, Authentication, quality control, standardization, consumer awareness and post marketing surveillance are the key points which could ensure the quality, safety and effectiveness of Ayurvedic medicines.[5,6]

Development of suitable dosage forms of ayurvedic or herbal drugs is still a challenging task. Some primary constraints for developing an appropriate delivery system are limited solubility and permeability of herbal drugs through biological membranes. Therefore, it produces little therapeutic efficacy and bioavailability. Research is now being concurrently conducted on basic as well as applied fields of herbal medicines, and this has create the need for studies in the delivery system of herbal drugs for maximum bioavailability.[7] The biological half life has an immense role in the therapeutic efficacy and potency of drug molecules at the site where it is administered. If the drugs have shorter t1/2 than it possesses low bioavailability as compared to higher t1/2 values. The biological membrane permeability offers more activity for a lipophilic drug. Hence, its chances of availability in the blood/ plasma are more in comparison to the hydrophilic drug. However, number of the active pharmaceutical ingredients obtained from high-throughput screening are poorly soluble. Lower bioavailability results from poor solubility and incomplete dissolution in vivo. These are often holding back continuous development and coming into the market of some promising new chemical entities.[8]

MATERIALS AND METHODS

Solanum Trilobatum, Lactose (Nice), Tragacanth (Chempure), Magnesium stearate, (Chemico) Polyvinyl pyrolidone (Nice), Talc (Nice).

COLLECTION OF PLANT SAMPLE

The *solanumn trilobatum* linn powder was collected from the komarapalayam local market which act as anti inflammatory, rejuvenating, antistress, antioxidant, mind-boosting and anti-tumor, anti asthmatic.

EXTRACTION PROCEDURE

Following that, 100g of the powder was extracted with water and it was stand for over night. Boiled in water at 1:5 ratio at 100°C for 30minutes.The mixture was extract filtered through Whatman no.1 filter paper to remove all unextractable matter, including cellular materials and others constitutions. The entire fitrate was concentrated to dryness using hot air oven to form powder.[9]

COMPATABILITY STUDIES

a) Infrared spectroscopic studies

Infrared spectrum of crude drug of *solanum trilobatum*, its physical mixture and crushed *solanum trilobatum* tablet are obtained using infrared spectrophotometer (FT-IR 8400s Shimadzu, Japan). Samples are prepared using KBr disc method and spectra are recorded over the range 400-4000 per cm. Spectra are analyzed for drug-excipient interaction.

2.3. PREFORMULATION STUDIES[10]

a) Organoleptic properties

Organoleptic properties of the *Solanum trilobatum* sample were studied by visual inspection.

b) Melting point determination

Melting point of drug sample was determined by using melting point apparatus. A few quantities of drug sample was taken and placed in a thin walled capillary tube; the tube was approximately 10-12 cm in length with 1mm in diameter and closed at one end. The capillary which contains sample was placed in melting point apparatus and heated and when drug sample was melted the melting point of sample powder was noted.

c) pH Determination

This was done by shaking a 1% w/v dispersion of the sample in water for 5min and the pH determination using a digital pH meter.

d) Loss on Drying

Weigh about 1.0g of sample, dry it at 105ºC for 3~4hrs.Cool for 30±5 minutes. It loses not more than 0.5% of its weight. Calculate as following formula,

$$\text{Loss on Drying \%} = m1\text{-}m2 / m1\text{-}m \times 100\%$$

Where:

m1- the weight of weighing bottle and sample

m2 - the weight of sample and weighing bottle after drying

m - the weight of weighing bottle dried to constant weight

e) Determination of solubility

Qualitative solubility analysis of *Solanum Trilobatum* extract were done by dissolving 5 mg of drug in 5 ml of distilled water and different solvents such as HCl (0.1N), Saline phosphate buffer (pH 7.4), Phosphate buffer(pH 6.8), ethanol, acetone and chloroform were used to determine the solubility of drug.

f) Angle of repose

Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and the horizontal plane. In the method, a fixed funnel method procedure is performed in triplicate and average angle of repose is calculated.

$$\text{Tan } \theta = h/r$$

$$\theta = \tan^{-1}(h/r)$$

g) Bulk Density

Bulk density is the ratio between given mass of powder and its bulk volume. Bulk density is carried out in triplicate. Bulk density measurements are carried by placing fixed weight of powder in graduated cylinder and volume occupied is measured and initial bulk density is calculated. It is expressed in gm/ml. Bulk density is calculated by using following formula,

Bulk Density = Mass of the powder / Bulk volume of the powder

h) True Density

True density is the ratio between given mass of powder and constant volume of powder after tapping. True density measurements are carried by cylinder is then tapped at a constant velocity till a constant volume is obtained. Then tapped density is calculated by using following formula

True density = Mass of the powder / Tapped volume of the powder

i) Carr's Index

Flow ability is assessed from Carr's compatibility index (C1%). The CI is calculated from the poured (bulk density) and tapped densities. Tapped density is measured by tapping fixed weight of the sample into 100ml measuring cylinder several times using a tap density apparatus till a constant volume is obtained, where the powder is considered to reach to it most stable arrangement. Carr's compressibility index is then calculated using the following formula,

Carr's index = Tapped density – bulk density x 100 / Tapped density

j) Hausner ratio

Hausner ratio is the ratio of tapped density to bulk density. Lower the value of Hausner ratio, better is the flow property. It is calculated by the following formula

Hausner's ratio = Tapped density / Bulk density

2.4. PREPARATION OF SOLANUM TRILOBATUM AYURVEDIC TABLET

Wet granulation method

Weigh all ingredients accurately, mix well and triturate by using mortar and pestle. The prepared 1% lactose was added slowly to form a damp mass. Damp mass was transfer through sieve no. 12. Prepared granules are dried in hot air oven. The completely dried granules are ready for compression.

Table 6: Formulation chart.

S. No	Ingredients	ST1	ST2	ST3	ST4	ST5	St6
1.	Solanum Trilobatum	12.5	12.5	12.5	12.5	12.5	12.5
2.	Polyvinyl pyrolidone	0.5	0.45	0.4	0.35	0.3	0.25
3.	Magnesium stearate	0.15	0.20	0.25	0.30	0.35	0.40
4.	Lactose	2.8	2.8	2.8	2.8	2.8	2.8
5.	Tragacanth	0.15	0.15	0.15	0.15	0.15	0.15
6.	Talc	0.15	0.15	0.15	0.15	0.15	0.15
7.	Total	16.25gm	16.25gm	16.25gm	16.25gm	16.25gm	16.25gm

2.5. POST FORMULATION STUDIES

a) Weight variation

Twenty tablets (n ¼ 20) from each batch were weighed using electronic balance and their average weight was calculated.

b) Hardness

Tablet requires a certain amount of hardness and resistance to friability to withstand mechanical shakes of handling in manufacturing, packing and shipping. The hardness of tablet is determined using Monsanto hardness tester. It is expressed in Kg/cm^2. Three tablets are selected from each formulation and hardness of tablet is determined. The results are expressed in average value.

c) Thickness

Thickness gauge or tester is an instrument that measures the thickness of tablets or capsules in millimetres. To measure the tablet thickness simply place the tablet in between the jaws and slide the scale jaw to press the tablet against the stationary jaw. The reading on the display is noted and it is the actual thickness of the tablet.

d) Friability test

The friability of tablets is determined using Roche Friabilator. Twenty tablets were randomly selected from each formulation and initial weight of 20 tablets are calculated, then transferred into Friabilator. The Friabilator is operated at 25 rpm for4 minutes (100 revolutions). The tablets dedusted and weighed again (final weight). The percentage friability is calculated by the following equation

Friability (%) = Initial weight – Final weight x 100 / Final weight

Compressed tablet that loses less than 0.1% to 0.8% of the tablet weight are considered acceptable.

e) Disintegration Study

This test was a time required for the tablet to separate into particles, the disintegration test measure only of the time required under a given set of a conditions for a group of tablets to disintegrate into particles. This test was performed to identify the disintegration of tablet in a specific time period.[11][12]

f) In vitro dissolution studies

In vitro release studies of *Solanum Trilobatum* tablets are performed by using USP type II Paddle dissolution apparatus in 900 ml of phosphate buffer pH 7.4 maintained at 37° C ± 1° C and 50 rpm. Samples (5 ml) are withdrawn at regular intervals of 5 minutes for 30minutes and the same volume of fresh dissolution medium is replaced after every withdrawal. The withdrawn samples are analysed by UV- visible spectrophotometer (Shimadzu UV-1700 pharma spec, Japan) at 424 nm(λmax). The studies are done in triplicate.[13]

RESULTS AND DISCUSSION

COMPATABILITY STUDIES

The FTIR spectra of **solanum Trilobatum extract,** and its physical mixture showed no significant interaction between drug and polymers. The FTIR spectra's of solanum Trilobatum and physical mixture are shown in fig. 14, 15, 16, 17, 18, 19 & 20.

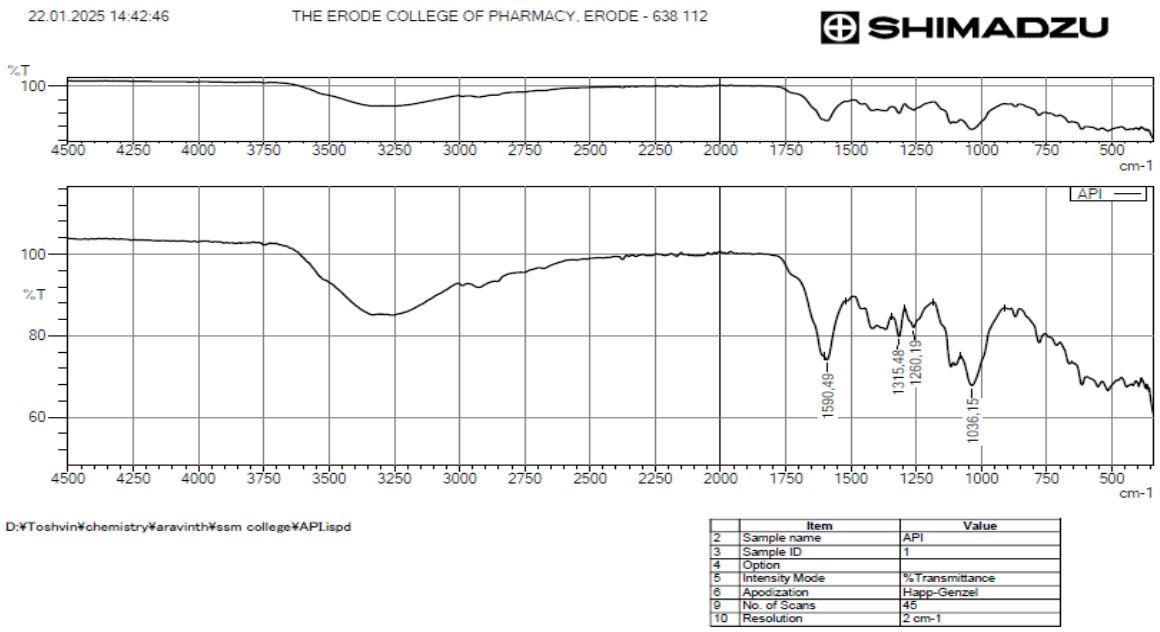


Fig. 1: FTIR spectra of solanum Trilobatum.

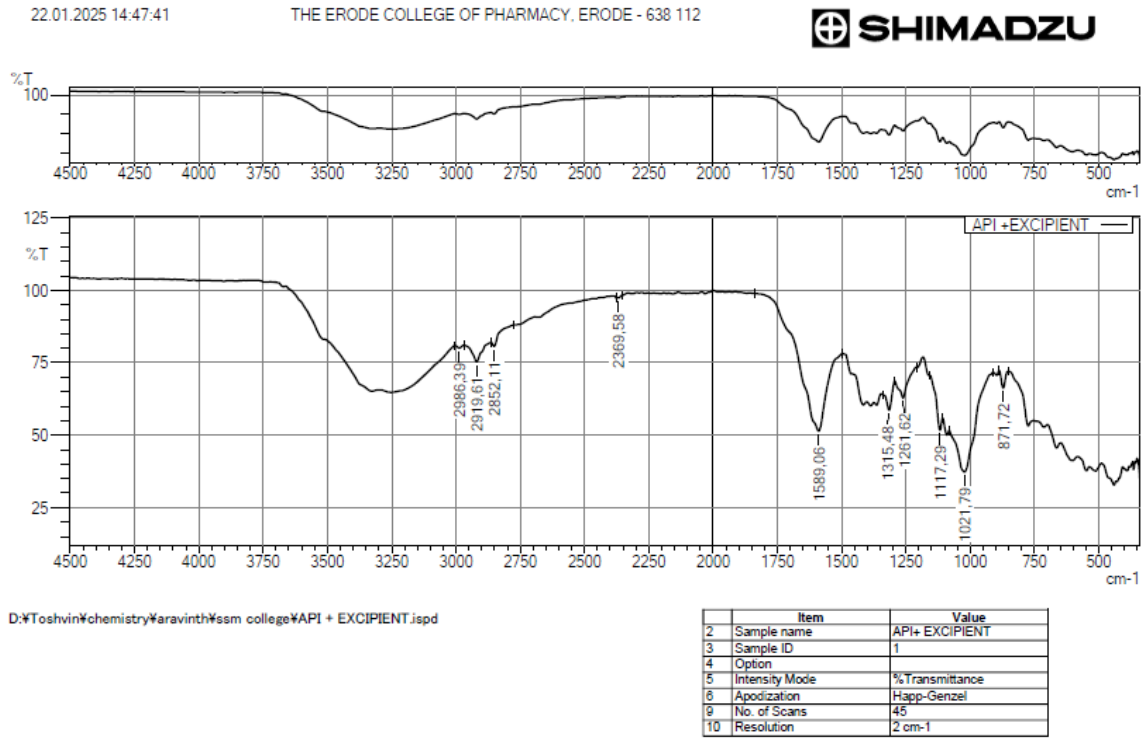
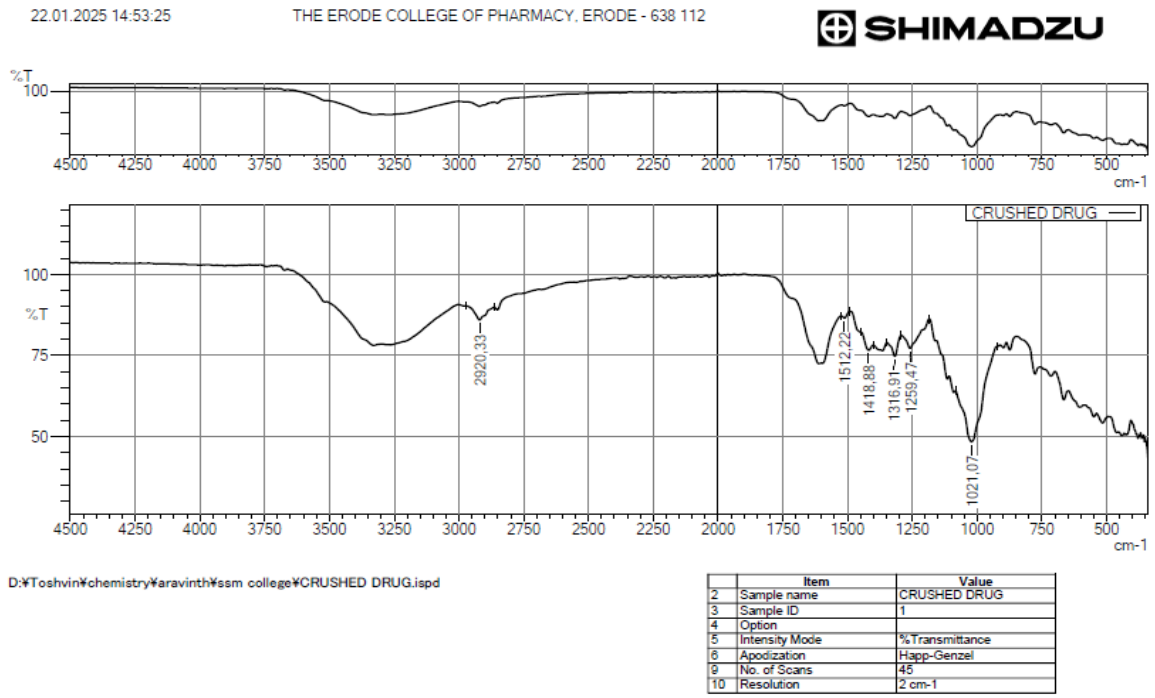


Fig. 2: FTIR spectra of Physical Mixer.



	Item	Value
2	Sample name	CRUSHED DRUG
3	Sample ID	1
4	Option	
5	Intensity Mode	%Transmittance
6	Apodization	Happ-Genzel
9	No. of Scans	45
10	Resolution	2 cm-1

Fig. 3: FTIR spectra of Crushed solanum Trilobatum Tab.

FORMULATION TABLETS

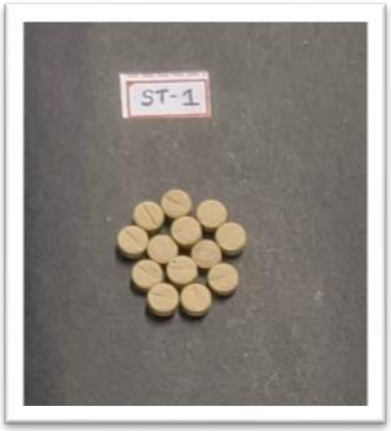


Fig. 4: ST1.

Fig. 5: ST2.

Fig. 6: ST3.

Fig. 7: ST4.

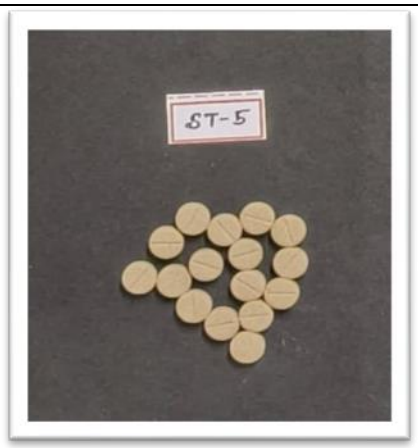


Fig. 8: ST5

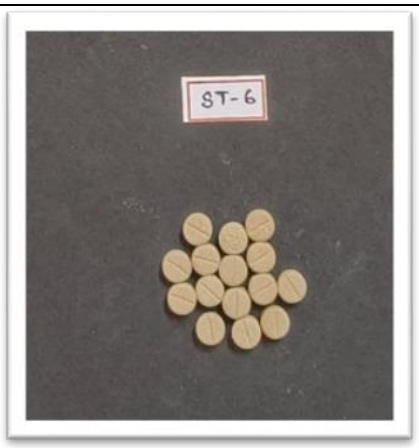


Fig. 9: ST6.

3.3 PREFORMUATION STUDIES

Organoleptic properties

Organoleptic properties of the drug sample were found to be as given in table below.

Table 8: Organoleptic properties of Solanum Trilobatum extract.

Parameters	Reported value	Observed value
Colour	Greenish powder	Greenish powder
Texture	Moderately coarse powder	Moderately coarse powder
Taste	Slightly bitter in taste	Slightly bitter in taste
Odour	Slightly bitter and earthy	Slightly bitter and earthy

Melting point Determination

Melting point of solanum trilobatum was determined by capillary method. The melting point of solanum trilobatum was found to be 148^0, Which complied with IP Standard, Including Purity of the drug sample.

pH Determination

pH was found to be 7.1, which complied with IP Standard, including purity of the drug sample.

Loss on Drying

Loss on drying of API was found to be 0.03% of its original weight.

Determination of solubility

Results of solubility of the drug in different solvents are given below in table:

Table 9: Solubility of solanum trilobatum in various solvents.

Solvents (5 ml)	Solubility of the drug (5 mg)
Distilled water	Soluble
0.1N HCL	Slightly soluble
6.8 PH Buffer	Poorly soluble
7.4 PH Buffer	Soluble
Ethanol	Slightly soluble
Methanol	Poorly soluble
Chloroform	Poorly soluble
Acetone	Insoluble

Determination of Angle of repose, Bulk density, Tapped density, Carr's index and Hausner's ratio

Table 10: Determination of powder flow property.

Pre formulation parameters	ST1	ST2	ST3	ST4	ST5	ST6
Angle of repose (θ)	16.31	16.56	17.10	17.35	18.17	20.10
Bulk density g/cm^3	0.267	0.29	0.20	0.30	0.18	0.15
Tapped density g/cm^3	0.327	0.33	0.23	0.35	0.25	0.29
Hauser's ratio	1	1.04	1.08	1.05	1.03	1.07
Carr's index (%)	4.1	7.4	6.7	5	4.8	6.5

*Each value is an average of three determinations SD – standard deviation.

The angle of repose for the formulated granules was carried out and the results were shown in table no.10. It concludes all the formulations blend was found to be in the range 23.86^0 to 25.21^0.

Compressibility index was carried out, and it was found between 5.53% and 7.52% indicating the powder blend has the required flow property for compression.

Hausner's ratio values were found below 1.25, indicating the powder blend has the good flow property.

After the evaluation of granules according to the procedure and table no.6. The tablets were prepared by Direct compression method.

3.4 POST FORMULATION STUDIES

Determination of weight variation, Hardness, Thickness, Friability, Disintegration Time of ST1 to ST6

Table 11: Evaluation of Physical parameters of the formulated tablet.

Parameters	ST1	ST2	ST3	ST4	ST5	ST6
Weight Variation	5±0.25	4.8±0.63	4.9±0.52	5±0.34	4.5±0.61	4.1±0.53
Friability (%)	0.3±0.37	0.2±0.71	0.6±0.58	0.7±0.27	0.5±0.41	0.4±0.69
Hardness (kg/cm^2	3±0.72	2.9±0.61	2.7±0.52	2.4±0.72	2.8±-0.74	3.1±0.81
Disintegration (MIN)	8±0.31	8±0.52	7±0.52	9±0.61	7±0.75	9±0.16
Tablet thickness	0.73±0.027	0.81±0.052	0.83±0.061	0.71±0.074	0.76±0.063	0.72±0.058

* Each value is an average of three determinations SD - standard deviation

The measured hardness of tablets of each batch ranged between 8.32 to 10.57 kg/cm^2, which ensures good handling characteristics of all batches.

The % friability was less than 1% in all the formulations ensuring that the tablets were mechanically stable.

All the formulated tablets passed weight variation test as the % weight variation was within the pharmacopeial limits of ±7.5% of the weight.

The percentage of drug content for the formulated tablets were found between 98.54% to 98.75% of *solanum trilobatum*, which complies with official specifications.

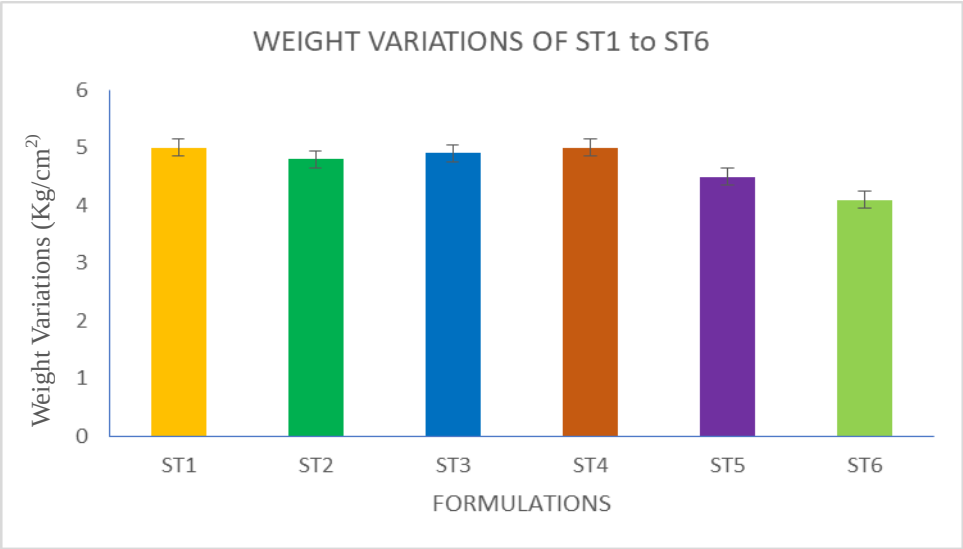


Fig. 10: Weight Variation of ST1, ST2, ST3, ST4, ST5 & ST6.

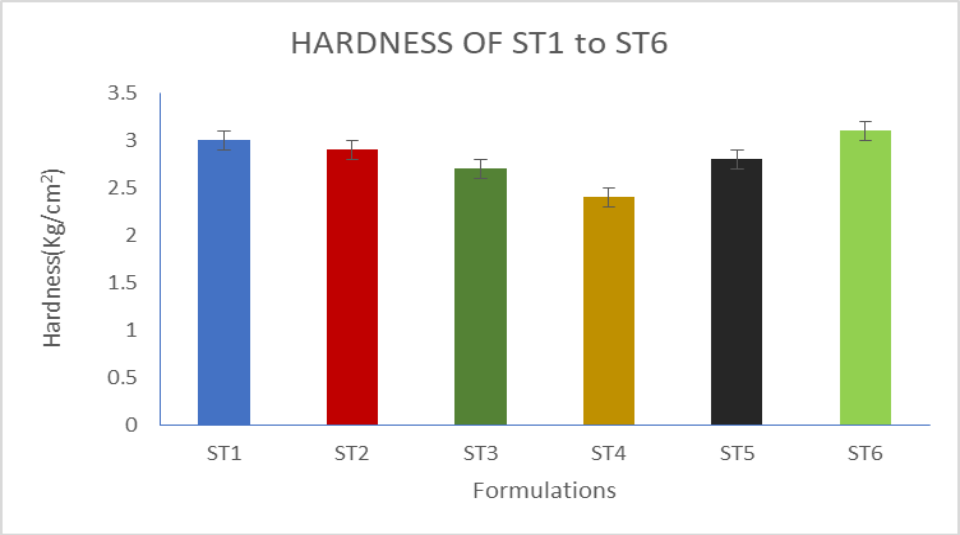


Fig. 11: Hardness of ST1, ST2, ST3, ST4, ST5 & ST6.

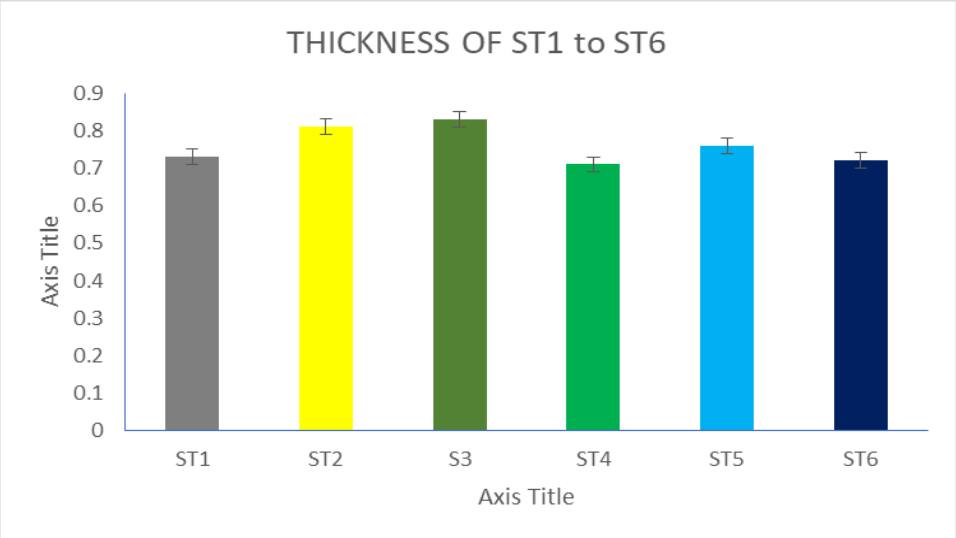


Fig. 12: Thickness of ST1, ST2, ST3, ST4, ST5 & ST6.

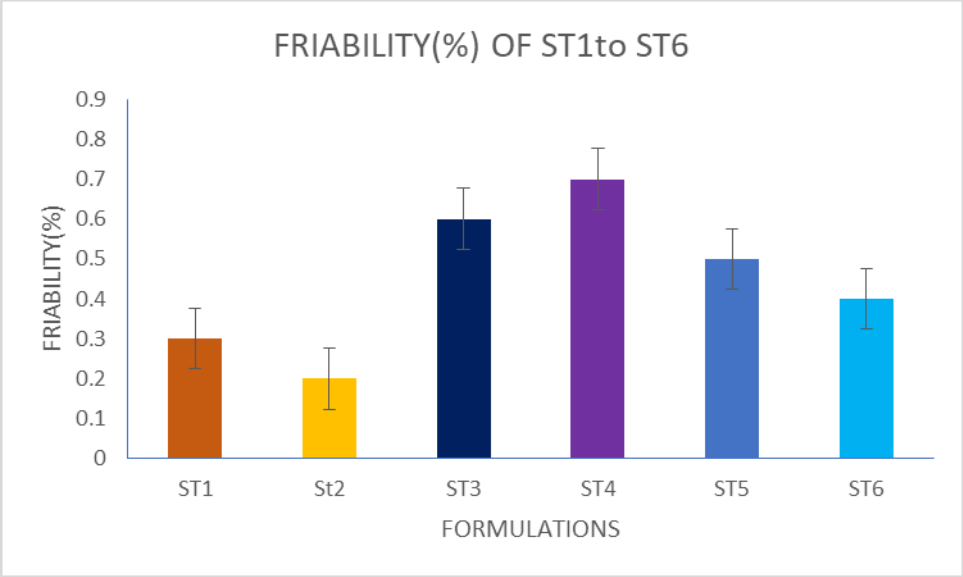


Fig. 13: Friability of SF1, SF2, SF3, NF1, NF2 & NF3.

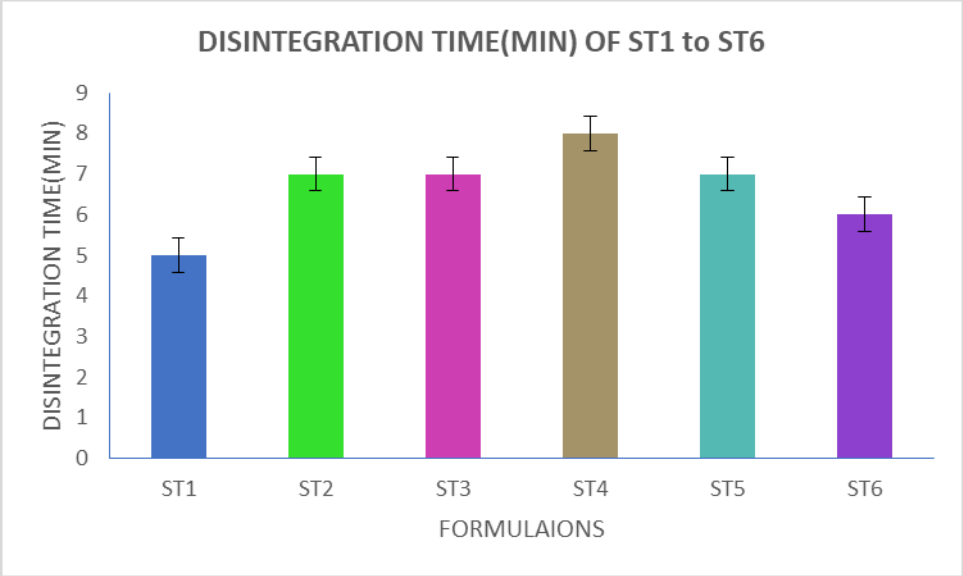


Fig. 14: Disintegration Time of ST1, ST2, ST3, ST4, ST5, ST6.

Determination of Invitro drug dissolution studies

Table 12: Invitro drug dissolution studies of the formulated tablets.

Time (Minutes)	Cumulative percentage drug release					
	ST1	ST2	ST3	ST4	ST5	ST6
0	0	0	0	0	0	0
5	35.01	31.14	29.36	28.17	21.22	24.20
10	49.13	41.87	47.04	45.05	42.06	36.10
15	68.39	64.99	56.25	57.24	50.27	47.29
20	72.45	72.43	67.96	66.86	62.87	57.90
25	82.79	82.76	79.08	79.27	71.30	68.31
30	98.59	93.31	92.50	94.48	90.86	89.35

The batches containing (ST1-ST3), showed the effective sustain release property but the drug release was ineffective in ST2 and ST3. ST1 satisfied the condition of, sustained and effective release.

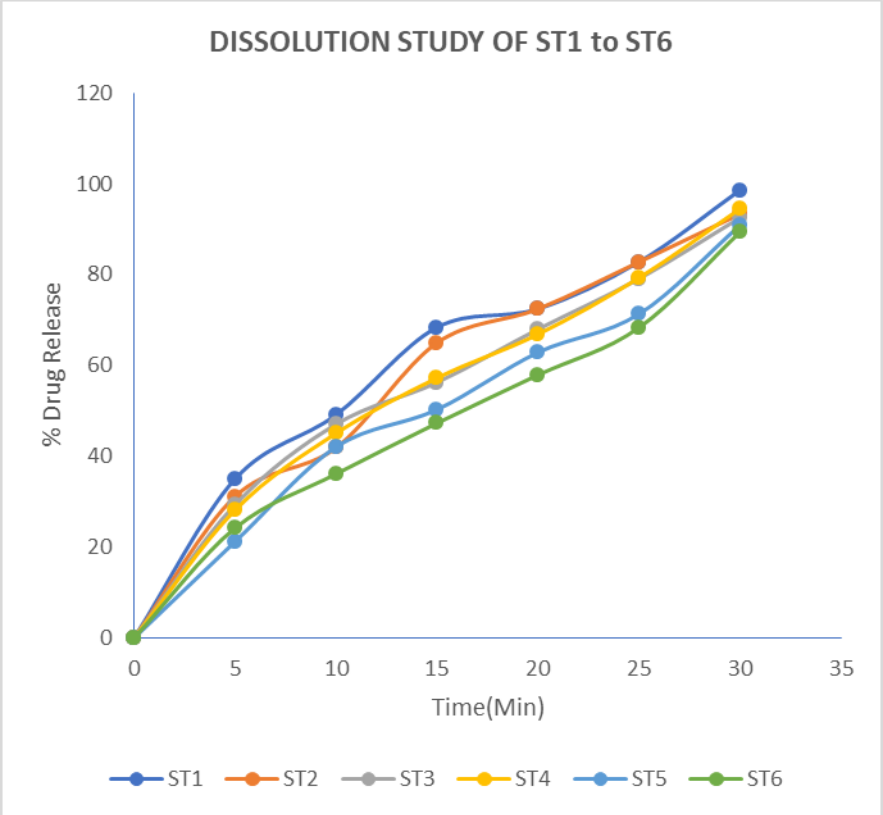


Fig. 15: Percentage Drug release of ST1, ST2, ST3, ST4, ST5, ST6.

CONCLUSION

The study was conducted to the Ayurvedic Solanum trilobatum tablets formulation was developed using a standardized extract of Solanum trilobatum, a herb traditionally used in Ayurvedic medicine. The formulation was optimized through a series of experiments, including powder characterization, tablet compression, and dissolution testing. The results showed that the optimized formulation exhibited good tablet properties, including hardness, friability, and disintegration time. The dissolution testing revealed that the formulation released the Solanum trilobatum extract in a conventional manner. The Ayurvedic Solanum trilobatum tablets formulation developed in this study demonstrated good tablet properties and controlled release of the Solanum trilobatum extract. The formulation has the potential to provide therapeutic benefits for various health conditions, including respiratory issues, digestive problems, and inflammatory diseases. The use of a standardized extract and the optimized formulation make this product a promising alternative to conventional medication.

BIBLIOGRAPHY

1. *Ratnaparkhi M. P., Gupta Jyoti P., Sustained Release Oral Drug Delivery System - An Overview, International Journal of Pharma Research & Review, Mar 2013; 2(3): 11-21.
2. Krishnamachary, B., Rajendran, N., Pemiah, B., Krishnaswamy, S., Krishnan, U.M., Sethuraman, S., Sekar, R.K., Scientific validation of the different purification steps involved in the preparation of an Indian Ayurvedic medicine, Lauhabhasma. J. Ethnopharmacol, 2012; 142: 98–104.
3. Mukherjee, P.K., Houghton, P.J., The worldwide phenomenon of increased use of herbal products: opportunity and threats. In: Mukherjee, P.K., Houghton, P.J.(Eds.), Evaluation of Herbal Medicinal Products - Perspectives on Quality, Safety and Efficacy. Pharmaceutical Press, London, 2009; 3–12.

4. Mukherjee, P.K., Nema, N.K., Venkatesh, P., Debnath, P.K., Changing scenario for promotion and development of Ayurveda – way forward. J. Ethnopharmacol, 2012; 143: 424–434.
5. Mukherjee, P.K., Bahadur, S., Harwansh, R.K., Chaudhary, S.K., Shifting paradigm for validation of medicinal plants in Indian traditional medicine. Indian Drugs, 2014; 51: 5–14.
6. Mukherjee, P.K., Bahadur, S., Chaudhary, S.K., Kar, A., Mukherjee, K., Quality related safety issue-evidence-based validation of herbal medicine farm to pharma. In: Mukherjee, P.K. (Ed.), Evidence Based Validation of Herbal Medicine. Elsevier, Amsterdam, 2015; 1–28.
7. Mukherjee, P.K., Houghton, P.J., The worldwide phenomenon of increased use of herbal products: opportunity and threats. In: Mukherjee, P.K., Houghton, P.J.(Eds.), Evaluation of Herbal Medicinal Products - Perspectives on Quality, Safety and Efficacy. Pharmaceutical Press, London, 2009; 3–12.
8. Rahman, M.A., Hussain, A., Iqbal, Z., Harwansh, R.K., Singh, L.R., Ahmad, S., Nanosuspension: a potential nanoformulation for improved delivery of poorly bioavailable drug. Micro Nanosyst, 2013; 5: 273–287.
9. Ignácio SR, Ferreira JL, Almeida MB, Kubelka CF. Nitric oxide production by murine peritoneal macrophages in vitro and in vivotreated with Phyllanthustenellus extracts. J Ethnopharmacol, 2001; 74: 181-7.
10. Micheal E Aulton. Aulton's pharmaceutics: the design and manufactured of medicines, 3rd editions China; Elsevier publishers, 2007; 178: 355-356.
11. Haritha B. A review on evaluation of tablets. J Formulation Sci Bioavailability, 2017; 1: 107.
12. Hitesh Chaturvedi, Ayush Garg, Udiabhan Singh Rathore. Post-compression evaluation parameters for tablets-an overview. Eur J Pharm Res, 2017; 4: 526-30.
13. Habib W, Khankari R, Hontz J, Fast-dissolving drug delivery systems, critical review in therapeutics, Drug Carrier Systems, 2000; 17, 61.