International Journal of Pharmacognosy and Pharmaceutical Research

ISSN Print: 2664-7168
ISSN Online: 2664-7176
Impact Factor: RJIF 8.2
IJPPR 2025; 7(2): 107-121
www.pharmacognosyjournals.com
Received: 09-06-2025
Accepted: 11-07-2025

Dev Soni
Assistant Professor, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Jashoda Prajapati
Assistant Professor, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Dr. Viral A Prajapati
Assistant Professor, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Mayur Bathvar
Assistant Professor, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Patel Harsh
Student, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Jani Shreyanshi
Student, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Dudhat Aenshi
Student, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Panchal Disha
Student, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Parmar Vipul
Student, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Corresponding Author:
Dev Soni
Assistant Professor, Shree Swaminarayan Sanskar Pharmacy College, Near Zundal Circle, S.P. Ring Road, Between Chandkheda - Adalaj Zundal, Gandhinagar, Gujarat, India

Optimization of kalmegh and Parijat-based fast dissolving herbal tablets for hyperlipidemia management using a two-level three-factorial design

Dev Soni, Jashoda Prajapati, Viral A Prajapati, Mayur Bathvar, Patel Harsh, Jani Shreyanshi, Dudhat Aenshi, Panchal Disha and Parmar Vipul

DOI: https://DOI.org/10.33545/26647168.2025.v7.i2b.124

Abstract
Hyperlipidemia, characterized by elevated levels of lipids in the blood, is a leading risk factor for cardiovascular diseases such as atherosclerosis, coronary artery disease, and stroke. Conventional pharmacotherapy, including statins and fibrates, though effective, often presents undesirable side effects, such as hepatotoxicity and muscle weakness. In this context, the use of herbal medicines as safer alternatives has gained considerable interest. The present research focuses on the formulation, optimization, and evaluation of fast-dissolving herbal tablets (FDTs) incorporating Kalmegh (*Andrographis paniculata*) and Parijat (Nyctanthes arbor- tristis)—two plants traditionally known for their antihyperlipidemic, antioxidant, and hepatoprotective properties.The study utilized a two-level, three-factor factorial design (2^3) to investigate the influence of three independent variables—binder (microcrystalline cellulose), disintegrant (sodium starch glycolate), and lubricant (magnesium stearate)—on key response variables such as disintegration time, drug release, and assay value. The herbal extracts were obtained via hydroacetone extraction, and a calibration curve was established for standardization. The tablets were prepared using the direct compression method and were evaluated for pre-compression (flow properties, bulk density) and post-compression parameters (hardness, friability, weight variation, disintegration time, wetting time, and dissolution rate).Among the trial batches (T_1-T_8), the optimized formulation demonstrated a rapid disintegration time (<30 seconds)and cumulative drug release of up to 90% within 5 minutes, indicating excellent performance as a fast-dissolving dosage form. The formulation pharmacopoeial standards, and the observed results confirmed the synergistic lipid-lowering effect of Kalmegh and Parijat. This was likely due to the presence of bioactive compounds such as andrographolide in Kalmegh and flavonoids and phytosterols in Parijat, which have been previously reported to lower LDL, total cholesterol, and triglyceride levels, while promoting HDL cholesterol. The study concludes that the herbal FDTs of Kalmegh and Parijat offer a promising, natural alternative to conventional antihyperlipidemic therapy. Their fast disintegration, high bioavailability, and favorable release profile make them suitable for patients who require quick therapeutic action and enhanced compliance. Additionally, the factorial design approach facilitated the precise optimization of excipient levels to ensure robust tablet performance. Future studies could include *in vivo* lipid profile testing and stability studies to support further development toward clinical application.

Keywords: Fast-dissolving herbal tablets, Kalmegh, Parijat, hyperlipidemia management, factorial design, lipid-lowering, antihyperlipidemic, tablet optimization, herbal extracts, drug release

Introduction

Introduction of Hyperlipidemia

Hyperlipidemia is a medical condition characterized by an increase in one or more of the plasma lipids, including triglycerides, cholesterol, cholesterol esters, phospholipids and or plasma lipoproteins including very low-density lipoprotein and low-density lipoprotein along with reduced high-density lipoprotein levels. This elevation of plasma lipids is among the leading risk factors associated with cardiovascular diseases. In the meantime, statins and fibrates remain the major anti-hyperlipidemic agents for the treatment of elevated plasma cholesterol and triglycerides respectively, with the price of severe side effects on the

musclesand the liver. The present review focuses mainly on the types of hyperlipidemias, lipid metabolism, treatments and new drug targets for the treatment of elevated lipid profile. Many agents such as lanosterol synthase inhibitors, squalene epoxidase inhibitors, diacyl glycerol acyl transferase inhibitors, ATP citrate lyase inhibitors have shown a promising potential in the treatment of hyperlipidemia in clinical trials.

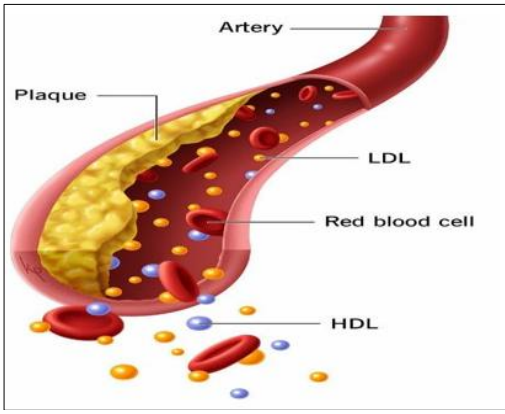

Fig 1: Hyperlipidemia condition

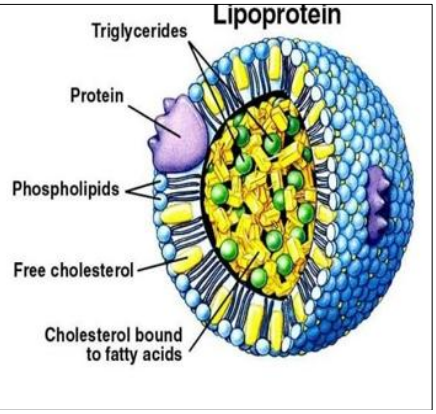

Fig 2: Structure of Lipoprotein

Plasma lipoproteins Composition and structure:
Lipoproteins are macromolecules aggregate composed of lipids and proteins; this structure facilitates lipids compatibility with the aqueous body fluids. Lipoproteins composed from non-polar lipids (triglycerides and cholesteryl esters), polar lipids (phospholipids and unesterified cholesterol) and specific proteins known as apo lipoproteins. Apolipoproteins are amphiphilic proteins that bind to both lipids and the plasma.

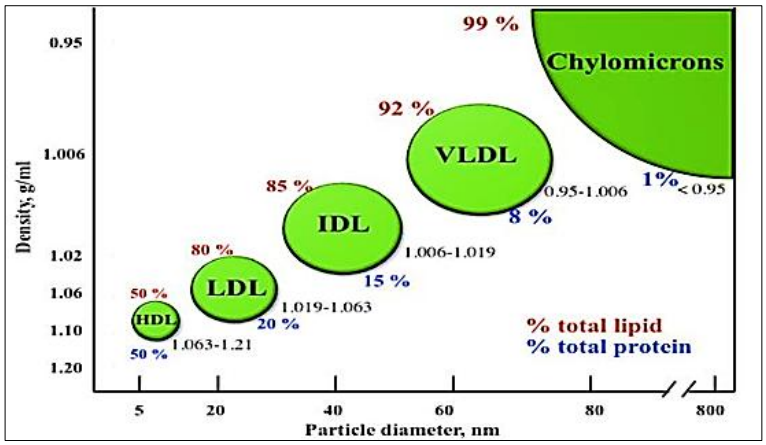

Fig 3: Brief classification of Lipoprotein

Lipoprotein classification
- Chylomicrons (CM)
- very low-density lipoproteins (VLDL)
- low-density Lipoproteins (LDL)
- intermediate-density lipoproteins (IDL)
- high-density lipoproteins (HDL)

Sign and Symptoms
Hyperlipidaemia often doesn't show any symptoms, which is why it's sometimes called a "silent" condition. However, when symptoms do appear, they can include:
High blood pressure, Dizziness**,** Chest pain, **S**hortness of breath**,** Numbness or tingling in the limbs**,** Slow wound healing**,** Small fatty deposits under the skin (called xanthomas), usually around the eyes, Poor wound healing

Fast Dissolving Tablets
Fast dissolving tablets (FDTs), also known as orally disintegrating tablets (ODTs), are solid dosage forms that rapidly disintegrate or dissolve in the mouth without the need for water. This unique formulation is particularly beneficial for populations such as paediatrics and geriatrics, who may have difficulty swallowing traditional tablets or capsules. The convenience of FDTs enhances patient compliance, making them a popular choice in modern pharmaceutical applications. Oral route of administration is most preferred route for administration of various drugs due to it is regarded as safest, most convenient and economical route. Tablets and capsule are widely consuming dosage forms for oral route of administration of various drugs because of its benefit of self-administration, compactness and ease of production. However, many patients group such as elderly, children and patients who are unamenable, feel like vomiting have difficulty in swallowing these dosage form. To overcome this problem fast dissolving tablet emerged as alternative dosage form. Fast dissolving tablets are also called as orodispersible tablet, rapimelt tablets, mouth dissolving tablets, quick dissolving tablets, rapid dissolving tablets, porous tablets etc. These tablets disaggregate in the mouth within a very short time interval i.e. 20-30 sec and comes in contact with saliva resulting in the pharmacological action of drug.

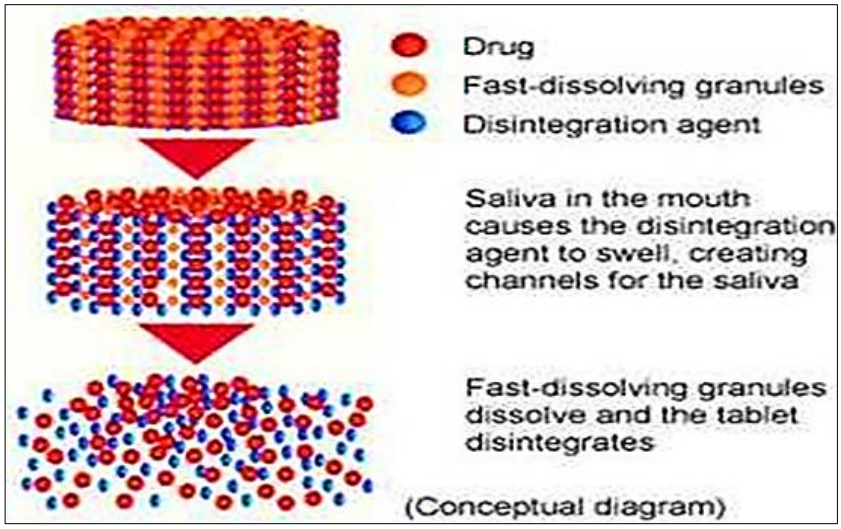

Fig 4: FDT Diagram

Fast dissolving tablets show better patient compliance and acceptance with improved bioavailability, efficacy and biopharmaceutical properties, in contrast to conventional tablets. Fast dissolving concept is a very supportive route for life-threating diseases patients like AIDS, Parkinson disease etc. United States Food and Drug Administration (USFDA) defined fast dissolving tablet (FDT) as "a solid dosage form containing a medicinal substance or active ingredient which disintegrates rapidly usually within matter of seconds when placed upon tongue". According to European Pharmacopoeia, "the FDT should disperse/disintegrates in less than three minutes". Fast dissolving tablets are available in two types that should be distinguished: While one tablet formulation rapidly dissolves in the mouth and can be ingested without the need for water, the other tablet formulation dissolves readily in water to form a dispersion that is simple for the patient to consume. In most cases, a tablet that dissolves or disintegrates in the oral cavity without the requirement for water or chewing is a fast-dissolving drug delivery system. Currently these fast-dissolving tablets are available in market for treating disease condition such as Parkinson's disease, schizophrenia, hypertension nausea, vomiting and migraine.

Advantages of fast dissolving tablets:

- Ease of administration to patients who cannot swallow, such as paediatric, geriatric and psychiatric patients.
- Good mouth feel property of fast dissolving tablets helps to modify the basic view of medication as "bitter pill", particularly for paediatric patients due to improved taste of bitter drugs.
- Advantage of liquid medication in the form of solid preparation.
- Ease of administration and accurate dosing as compared to liquid Formulations.
- Faster drug absorption through the mouth, throat, and oesophagus, which may result in a quick onset of action.
- By decreasing side effects, pre-gastric absorption can improve bioavailability, reduce dose, and improve clinical performance.
- Quick drug therapy intervention.
- Advantageous in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid onset of action required
- Adaptable and compatible with current packaging and processing machinery.
- Permit high drug loading, cost effective.
- Protection from the danger of suffocation due to physical obstruction, thus increasing protection.

Evaluation of Fast Dissolving Tablets

- **General appearance:** Tablets of different formulations were randomly selected and taste, shape, were evaluated.
- **Tablet thickness:** Tablet thickness is an important characteristic and is expressed in mm. The thickness and diameter of the tablets was determined using a micrometer screw gauge.
- **Tablet hardness:** Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet, the resistance of the tablet to abrasion, chipping or breakage under condition of storage transformation and handling before usage depends on its hardness. Hardness of the tablet was determined using Pfizer Hardness Tester.
- **Friability of tablets:** Friabilator consist of plastic chamber revolves at 25 rpm, dropping those tablets at distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 min. At the end of these test tablets are required to be dedusted and reweighed, the loss in the weight of tablet is the measured of friability and is expressed in percentage as-%

$$\text{Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

- **Weight variation:** 20 tablets are selected randomly from the lot and weighted individually to check for weight variation. Weight variation of tablet specification as per I.P.
- **Wetting time:** Five circular tissue papers of 10 cm diameter are placed in petri dish with a 10 cm diameter. Ten millimetres of water containing eosin, water soluble dye, is placed in petri dish. A tablet is carefully placed on surface on surface of tissue paper. The time

required for water to reach upper surface of tablet is noted as wetting time.

- ***In-vitro* disintegration time:** This test is performed on 6 tablets, by placing tablet into each tube(3 inches long and have 10 mesh screen) of apparatus using the distilled (used as disintegration medium) at a frequency of 28-32 cycle/minute and 37 ± 20 c and the time in second was noted when no lumps remaining in the apparatus.
- **Modified disintegration test:** The traditional method of conducting a disintegration test for these dosage forms has a number of drawbacks and is insufficient for measuring very quick disintegration times. Fast dissolving tablets need to have their disintegration times adjusted since they need to dissolve without water for the test, which should imitate salivary disintegration. A petri dish (10 cm in diameter) with 10 ml of water inside of it was used for this. The time it took for the tablet to totally break down into tiny particles was recorded after it was carefully placed in the centre of the petri dish.
- ***In-vitro* dispersion time:** To determine dispersion time 10 ml measuring cylinder was taken in which 6 ml distilled water was added and tablet was dropped in it. Time required for complete dispersion was determined.
- ***In-vitro* dissolution study:** *In vitro* dissolution study has to be performed by using USP type II apparatus (paddle type) [Electro lab (ETC -11L) Tablet dissolution tester] at 50 rpm. Phosphate buffer pH 6.8, 900 ml is mainly used as dissolution medium which is required to maintain at 37±0.5°C. Aliquot of (10ml) dissolution medium is required to withdraw out at specific time interval (2min) and then it is required to subject for process of filtration. The amount of drug dissolved was determined by UV Spectrophotometer (Shimadzu, Japan) by measuring the absorbance of the sample. Three trials of each batch were performed and average % drug release with standard deviation was calculated and recorded.

Ingredients Used

Table 1: List of Ingredients

Sr. No.	Ingredients	Quantity	Importance
1.	Extract kalmegh	7.5	Antimicrobial, Anticancer, Antidiabetic.
2.	Extract Parijat	7.5	Anticancer, Antioxidant, Anti-Inflammatory.
3.	Lactose	68.4	Filler, Lubricant, Improved Flowability
4.	SSG	6.0	Disintegration, Swelling Properties
5.	MCC	10.4	Binder, Diluent, Disintegrant
6.	MG Stearate	0.3	Lubricant

Kalmegh

Table 2: Details of kalmegh

Attribute	Details
Botanical Name	*Andrographis paniculata*
Kingdom	Plantae
Order	Lamiales
Family	Acanthaceae
Genus	Andrographis

Fig 5: kalmegh

Kalmegh (*Andrographis paniculata*)

Kalmegh, commonly known as the "King of Bitters," is a traditional medicinal herb native to South Asia. It has been utilized for centuries in Ayurvedic medicine for its numerous health benefits. Kalmegh is particularly valued for its hepatoprotective, anti-inflammatory, anti-hyperlipidaemic and antioxidant properties. Ayurveda is a medical science that gives us a profuse knowledge of Dravyas or drugs which we get from plants, animals and minerals. The medicinal plants are the potential source of Ayurvedic medicines and are a core component at primary health care level due to their availability, compatibility and affordability. India is perhaps the richest nation with regard to herbal medicinal wealth (about 15000-20000 plants have been found to have good medicinal value). And it also has the oldest medicinal system in the form of Ayurveda Ayurvedic classics have mentioned many efficacious herbs to treat a variety of ailments. One such herb is being Kalmegh i.e. *Andrographis paniculata* (*Burm.f.*) Wall. ex Nees, is a potent hepatoprotective and antifebrile herb. Modern studies have explicitly revealed that *Andrographis paniculata* has a wide range of pharmacological actions such as anti- inflammatory, anti-diabetes, anti- diarrheal, anti-viral, anti-malarial, hepatoprotective, anti- cancer, anti-human immunodeficiency virus (HIV), immune stimulator and anti-snakebite.

Kalmegh, meaning is "dark cloud" because of its appearance from a distance like a black cloud in the blue sky. It is also known as Bhui-neem, meaning "neem of the ground", since the plant, though being a small annual herb, has a similar strong bitter taste as that of the large Neem tree (*Azadirachta indica)*. In different geographical region Kalmegh i.e. *Andrographis paniculata* is termed as Bhunimba, Bhunimo, Desi chirayita etc. Glossary of Vegetable Drugs in Brihattrayi, mentioned that in Madhya Pradesh it is popular in the name of Bhunimba, but in Nagpur area and forests of Bihar it is termed as Chiraita. In Orissa it is called Bhunimba or Bhunimo. Renowned scholars of Ayurveda, Acharya PriyaVrat Sharma and Bapalal G. Vaidya also mentioned the Bhunimba as a synonym of Kalmegh.

In Adarsh Nighantu, Bapalal G. Vaidya has mentioned Kalmegh in Vasadi Varga with synonyms Kalpanath, Yavatikta and Shankhini. According to him Rasa of Kalmegh is Tikta and has Deepaniya, Katu-paushtik, Jwaraghna and Yakrit-rog Nashak Karma. Prof. PriyaVrat Sharma has mentioned Kalmegh in Shatpushpadi Varga with synonyms Bhunimba. Its fruits are Yava shaped and so it is mentioned as Yavatikta in some Nighantus. Its Rasa is Tikta, Guna is Laghu-Ruksha, Veerya is Ushna and Karma is Kapha-Pitta vinashini. According to him, it is used as Deepan, Swedan, Jwaraghna, Kriminashak and is helpful in Yakrit roga and Kushtha.

Pharmacological properties and therapeutic actions of Kalmegh

Ayurveda, the therapeutic-actions of any drug is based on its properties such as Rasa, Guna, Virya, and Vipaka. According to Ayurvedic Pharmacopeia of India the properties and actions of Kalmegh are listed below. Rasa (Taste)-Tikta (Bitter) Guna (Qualities)-Laghu (Light for digestion), Ruksha (Dry in nature) Veerya (Potency)-Sheet (Cold) Vipaka (Metabolic Property)-Katu (Transforms into Pungent/Spicy taste after digestion) Karma (Actions)-Kaphapitta shamaka (reduces vitiated kapha and pitta dosha), Dipana (appetizer), Pachana (digestive), Yakrut uttejaka (stimulates liver), Jwaraghna (antipyretic), Krimighna (wormicidal), Raktashodhak (purifies blood), Shothahar (reduces oedema), Svedajanana (stimulates sweating).

Botanical Characteristics

- **Scientific Name:** *Andrographis paniculata*
- **Family:** Acanthaceae.
- **Appearance:** Erect annual herb with dark green leaves and small white or purplish flowers.

Chemical Constituents

Andrographolide, neoandrographolide, andrograpanin, 12-didehydroandrographolide, are the principal chemical constituents found in the plant.

Active Compounds

The primary active constituent of Kalmegh is andrographolide, which is responsible for many of its therapeutic effects. Other compounds include:'

- Neoandrographolide
- Dehydroandrographolide
- Flavonoids
- Polyphenols
- These compounds contribute to Kalmegh's pharmacological activities, including its effects on lipid metabolism.

Collection method and time

Ayurvedic science gives great importance on the collection methods of the drugs. Time has its own importance in the procedure involved. The whole plant material (Panchang) of Kalmegh is used for its medicinal properties. It is collected when the entire plant is well grown and has full potency in the end of the rainy season (Varsha Ritu) or in the beginning of the winters (Sharad Ritu).

Formulations and Dosages

In Ayurveda, Kalmegha is used in the form of many formulations such as Churna kalpna (Powder form) 1-3 gms; Swaras (Juice): 5-10 ml; Kwath (Decoction): 20- 40 ml; Taral Satva (Liquid extract): 1/2-1 ml

Mechanisms of Action in Hyperlipidemia

Lipid Metabolism Regulation: Andrographolide has been shown to influence lipid metabolism by modulating key enzymes involved in lipid synthesis and degradation. This regulation helps lower levels of LDL cholesterol and triglycerides.

Antioxidant Activity

The antioxidant properties of Kalmegh protect against oxidative stress, which can lead to lipid peroxidation and subsequent cardiovascular damage. By reducing oxidative stress, Kalmegh supports healthier lipid profiles.

Improvement of Insulin Sensitivity

Insulin resistance is often associated with hyperlipidaemia. Kalmegh may enhance insulin sensitivity, thereby improving glucose metabolism and indirectly influencing lipid levels.

Bile Acid Secretion

Kalmegh promotes the secretion of bile acids from the liver, which aids in fat digestion and absorption. This process can help lower blood cholesterol levels.

Clinical Evidence Supporting Kalmegh's Use

Several studies have explored the effects of Kalmegh on lipid profiles:

- **Animal Studies:** Research involving animal models has demonstrated that Kalmegh extract significantly reduces total cholesterol and triglyceride levels while increasing HDL cholesterol.
- **Human Trials:** Some clinical trials have indicated that supplementation with Kalmegh can lead to favourable changes in lipid profiles among individuals with hyperlipidaemia.

Traditional Uses

In traditional medicine systems like Ayurveda, Kalmegh has been used not only for managing hyperlipidaemia.

Parijat (Nyctanthesarbor-tristis)

Table 3: Parijat details

Attribute	Details
Botanical Name	*Nyctanthes arbor-tristis*
Common Names	Parijata, Night Jasmine, Coral Jasmine, Tree of Sorrow
Kingdom	*Plantae*
Order	*Lamiales*
Family	*Oleaceae*
Genus	*Nyctanthes*

Fig 6: Parijat

Parijat (Nyctanthesarbor-tristis) Abstract

Ayurveda is an ancient school of medicine that employs the use of plants and their extracts to cure and manage a range of diseases. Every portion of the plant has medical value and can thus be profitably exploited. It is now considered as a valuable source of a variety of unique products for the manufacture of pharmaceuticals and industrial items for a

variety of diseases. The current research focuses on the plant N. arbour - tristis' potential phytochemicals and pharmacological action. As a result, the study's goal was to look into the chemical contents of the solvent leaf extracts as well as their anticancer and anti-inflammatory properties. The alkaloids, steroids, and other phytochemicals was discovered during the phytochemical screening of the plant. The extract had anticancer and anti-inflammatory properties. The biological activities observed in this study provide scientific confirmation for the ethno medicinal use of this plant.

Introduction

The Indian medicinal plant Nyctanthes arbortristis Linn. Of the family Oleaceae is very well known. It is regularly known as 'parijat', night jasmine, harsingar. Nyctanthes is Greek for 'night flower,' while arbortristis is Greek for' sad tree,' because it loses its radiance during the day. It is a traditional ethanol -medicinal plant not only in India and but also in Asia. It is native to India and can be found in large numbers below the Himalayas and south of the Godavari River. The leaves, flowers, bark, fruits and seeds of the plant all have diverse pharmacological qualities and are employed in alternative systems of medicine like Ayurveda, Sidha, and Unani. The entire plant, as well as individual sections, is utilized as herbal medicine for arthritis, malaria, spleen enlargement, and sciatica and blood purification.

It is a shrub or tree that's both common and wild, as well as hardy. Through *in vivo* and *in vitro* research, the purported traditional uses have been scientifically confirmed. The current review study will provide complete information on the chemical ingredients of this plant, as well as its pharmacological activity. N. Arbortristis is a sub-Himalayan plant that grows wild from Nepal to Chenabs, Burma Assam, Central India, Bengal, Rajasthan, Madhya Pradesh, Chhatanagpur, and south to the Godavari. It is grown in a variety of locations throughout India. It is moreover planted as a decorative plant in Indian gardens because of its fragrant blossoms. Its flowers bloom in the evening and fade in the morning. In its normal habitation, it grows gregariously and covers dry, low slopes and rocky gardens.

Higher plants have a distinct and diverse variety of biochemical compounds, which is why they are sometimes referred to as chemotherapeutic agent repositories. Because they have smaller amount of side effects, they can be used to develop natural medicines. Secondary metabolites are a chemistically and taxonomically varied category of chemicals with enigmatic functions that are widely used in research, agriculture, and human therapy. They are created through a sequence of metabolic processes from primary metabolites such as amino acids, carbs, and proteins. Alkaloids, flavonoids, glycosides, tannins, phenols, steroids, resins, saponins, and other phytochemicals are found in medicinal plants utilised by both humans and animals.

Antioxidants such as flavonoids, hydrolysable tannins, phenolic acids, and others have disease preventive properties. These fight free radicals that cause cancer, heart disease, mutagenic responses, and inflammatory reactions. The beginning of the word "Paarinaha Samudra thjaathova parijatah" He is known as Parijata because he was discovered in the samudra (ocean) after a long search (parinaha). Parijatha's mythological past the medication According to legend, Lord Shri Krishna brought a celestial tree to earth, known as Parijata. The tree is considered to be one of the five trees (Panchavrikshas) that decorated Lord Indra's Garden in Svargaloka, according to Indian mythology (heaven). In the Vishnu Purana, the storey of Parijatha is brilliantly depicted in relation to the account of Lord Krishna and his two wives. Satyabhama and Rukmini, Krishna's sisters, had a quarrel. Over the tree, over the tree, over the tree, over the tree, over the tree Krishna, on the other hand, planted this ornamental plant in the Satyabhama's yard so that when it bloomed, the blossoms fell in Rukmini's yard.

Taxonomical Classification

Table 4: Parijat details

Attribute	Details
Botanical Name	*Nyctanthes arbor-tristis*
Common Names	Parijata, Night Jasmine, Coral Jasmine, Tree of Sorrow
Kingdom	*Plantae*
Order	*Lamiales*
Family	*Oleaceae*
Genus	*Nyctanthes*

Propagation and Cultivation

Harsingar, or Nyctanthes arbor-tristis, is a plant that is often grown in gardens all across India, especially for its fragrant blossoms. In its native environment, it flourishes on rocky and arid hillsides and grows effectively at elevations of up to 1500 meters. Propagation can be done through seeds or seedlings, and the plant adapts well to various soil types and climatic conditions. Known for its fast growth, especially in its native environment, Harsingar is a versatile plant that requires minimal care once established.

Chemical Constituents

- **Leaves:** The leaves contain D-mannitol, βsitosterol, flavanol glycosides, astragalin, nicotiflorin, oleanolic acid, nyctanthic acid, tannic acid, ascorbic acid, methyl salicylate, an amorphous glycoside, an amorphous resin, trace of volatile oil, carotene, friedeline, lupeol, mannitol, glucose, carbohydrate, iriDOId glycosides, and benzoic acid.

- **Flowers:** The flowers include carotenoids, glycosides such as -monogentiobioside—D monoglucoside ester of -crocetin and - digentiobioside ester of -crocetin, as well as essential oils, nyctanthin, D-mannitol, tannins, glucose, and crocin-3 (or crocin-1). Seeds: Arbortristosides A and B, nyctanthic acid, 3,4-secotriterpene acid, glycerides of linoleic, oleic, lignoceric, stearic, palmitic, and myristic acids, as well as a water-soluble polysaccharide made of Dglucose and D-mannose, are all found in the seeds.

- **Seeds:** Arbortristosides A and B, nyctanthic acid, 3,4-secotriterpene acid, glycerides of linoleic, oleic, lignoceric, stearic, palmitic, and myristic acids, as well as a water-soluble polysaccharide made of D-glucose and D-mannose, are all found in the seeds. Bark: The bark contains mostly glycosides and alkaloids. Stem: Stem: and β-sitosterol.

- **Flower oil:** α-pinene, p-cymene, 1- hexanol methyl heptanone, phenyl acetaldehyde, 1- deconol.

Pharmacological actions and medicinal use of Parijat:

- Antioxidant activity
- Anti- viral activity
- Anti- plasmodial activity
- Anti- allergy activity
- Sedative activity
- Anti- leishmanial activity
- Anti- microbial activity
- Anti- arthritic activity
- Antiparasitic activity
- Antimalarial activity
- Immunostimulant activity
- Hepatoprotective activity
- CNS depressant action

Anti-hyperlipidemic activity

Increased blood lipid levels, or hyper lipidaemia, are the primary cause of many disorders, including atherosclerosis, coronary heart disease, ischemic cerebrovascular disease, hypertension, obesity, and type 2 diabetes. Wistar albino rats were used to test the antihyperlipidemic effect of NAT leaf methanolic extract. The extract significantly reduced triglycerides, total cholesterol, low density lipoproteins (LDL), very low-density lipoproteins (VLDL), and low-density lipoproteins (LDL) while significantly increasing high density lipoprotein (HDL) at dosages of 200 and 400 mg/kg body weight. Plant sterols (- stigmasterol and - sitosterol) that lower cholesterol absorption and enhance steroid excretion in the faeces may be responsible for the impact of decreasing blood lipid levels. We came to the conclusion that the methanolic extract of NAT leaves exhibited specific and non-specific antihyperlipidemic activity, which may have been caused by the presence of phytochemicals such phenol, triterpenoids, and flavonoids in the extract.

Benefits of key Ingredients: kalmegh and Parijat Kalmegh

- **Lipid-Lowering Effects:** Kalmegh contains active compounds like andrographolide, which have been shown to reduce total cholesterol, LDL (bad cholesterol), and triglyceride levels while potentially increasing HDL (good cholesterol).
- **Anti-Inflammatory Properties:** Chronic inflammation can contribute to lipid metabolism disorders.
- Kalmegh's strong anti-inflammatory effects help reduce vascular inflammation, improving lipid profiles and overall cardiovascular health.
- **Antioxidant Activity:** The herb has potent antioxidant properties that combat oxidative stress, a key factor in the development of atherosclerosis (plaque buildup in arteries) associated with hyperlipidaemia.
- **Liver Protection:** Kalmegh supports liver health, which plays a crucial role in lipid metabolism. A healthy liver can efficiently process fats, reducing the risk of lipid accumulation in the bloodstream.
- **Improved Insulin Sensitivity:** Some studies suggest that Kalmegh may improve insulin sensitivity, indirectly benefiting lipid metabolism, especially in individuals with metabolic syndrome.

Equipment

Table 5: List of equipments

Equipment	Source
Weighing Balance	Shimadzu or Sartorius
Double Cone Blender	Pyramid Engineering
single Sided Rotary Tablet Press	Cadmach or Rimek (Karnavati Engineering)
Hardness Tester	Monsanto
Dissolution Apparatus	Lab India
Friability tester	Electrolab
Disintegration Apparatus	Electrolab or Labindia

Materials

The Kalmegh and Parijat is procured from the Ayurvedic Chemist Shop, Ahmedabad and the MCC, SSG and Mg Stearate are obtained from the laboratory of SSSPC, Zundal.The Remaining Ingredients were acquired in an analytical grade.

Extraction of Herbal API

1. Extraction of Kalmegh

50 gm of kalmegh powder is taken which furtherly is dissolved in the 100 ml acetone along with the 50 ml of water. The mixture was agitated and subsequently left to settle in an area with reduced exposure to light for a duration of 5-7 days. Following this, the solution underwent filtration using cotton cloth, and the resulting filtrate was subsequently subjected to evaporation until complete dryness while under the Sunlight. The collected residues were subsequently dried.

2. Extraction of Parijat: 50 gm Parijat powder is taken and dissolved in the 100ml of acetone and 50 ml of water. The mixture was agitated and subsequently left to settle in an area with reduced exposure to light for a duration of 5-7 days. Following this, the solution underwent filtration using cotton cloth, and the resulting filtrate was subsequently subjected to evaporation until complete dryness while under the Sunlight. The collected residues were subsequently dried

Hydroacetone Extraction and Yield Optimization of Kalmegh and Parijat

Hydroacetone extraction was done on 50g of Kalmegh and Parijat using 100ml of Acetone, 50ml Water and 5% of hydroacetone extract was obtained. The physical characteristics of the extract, including colour and odour, were also analysed. The resulting Hydro acetone extract was Dark green and light brown in colour with a strong odour. Figure 7 shows the physical description of Hydroacetone Extract.

Fig 7: Hydroacetone extract of kalmegh and Parijat

Pre-Compression Parameters' Evaluation

In order to investigate the flow characteristics of a prepared blend intended for formulation, the evaluation of precompression parameters is an essential step. In order to ensure a thorough and in-depth study, each batch of prepared blend is put through a rigorous test to ascertain its precompression characteristics.

Angle of Repose

Angle of repose is indirectly showing the powder flow property. The highest angle between the surface of the pile of powder on the horizontal plane. There is an interparticle cohesion that interfere with flow property. The funnel method is been used to measure angle of repose. Funnel is fixed at height 'h', under this paper is kept and powder poured from funnel and it will form the pile of powder. When pile touch the funnel's tip, pouring of powder is being stopped. Radius 'r' of pile is drawn and measured on paper. Angle of repose is calculated by below formula;

$$tan\emptyset = \frac{h}{r}$$

Where

θ is the angle of repose in degrees h is the height of the pile of powder

r is the radius of the base of the pile of powder

Bulk Density

Bulk density gives the idea of powder packing in space without tapping. It is measured by particles pack loosely in space and gives the soft light density powder. Few particles are small in size and pack between large particles and provide the thick hard powder. Bulk density useful to determine capacity of instruments like granulating machine and blender to conduct further process. A weighed quantity of powder taken and filled into 100 ml measuring cylinder and height is measured. Formula for bulk density is given below;

$$Bulk\ Density = \frac{mass\ of\ powder}{Bulk\ volume\ of\ powder}$$

Where:

Mass of powder is the weight of the powder sample in grams

Bulk volume of powder is the volume occupied by the powder sample, including the inter- particle void spaces, in cubic centimeters (cc)

Tapped Density

It is a ratio of blend to tapped volume of blend, certain amount of blend weighed and poured into cylinder and height is measured. That cylinder placed on bulk density apparatus and mechanically tapped. Blend tapped for 500 time for first time and volume is registered, after that 750 time and 1500 time tapped by apparatus, final tapped volume is counted and calculate Tapped density.

$$\text{Tapped Density} = \frac{\text{Mass of powder}}{\text{Tapped volume of powder}}$$

Where:

Mass of powder is the weight of the powder sample in grams

Tapped volume of powder is the volume occupied by the powder sample after it has been subjected to mechanical tapping, in cubic centimeters (cc).

Car's Index / Compressible Index (CI).

Compressibility index done to know inter-particulate interaction and powder's ability to assemble. It depicts the ability of powder to decrease in volume under pressure using bulk and tapped density. Higher the compressibility index lowers the flow of powder or granules.

Hausner's Ratio

It is a ratio of tapped density and bulk density and indicates the flow property of powder.

$$Hausner's\ Ratio = \frac{Tapped\ Density}{Bulk\ Density}$$

Methodology & Preparation

Direct Compression Method

Selecting Ingredients

- **Extract Parijat:** Serves as the primary active ingredient, known for its anticancer, antioxidant, and anti-inflammatory properties.
- **Extract Kalmegh:** Acts as a secondary active ingredient, contributing antimicrobial, anticancer, and antidiabetic benefits.

- **Lactose:** Functions as a filler and lubricant, improving the flowability of the powder mixture during compression.
- **SSG (Sodium Starch Glycolate):** Acts as a disintegrant, promoting rapid tablet disintegration due to its swelling properties when in contact with liquid.
- **MCC (Microcrystalline Cellulose):** Serves as a binder and diluent, aiding in tablet compressibility and hardness.
- **MG Stearate (Magnesium Stearate):** Acts as a lubricant, preventing the powder from sticking to the tablet press during compression.

Drying and Sizing

Ensure that both the Parijat and Kalmegh extracts are properly dried to minimize moisture content, which can affect powder flow and tablet stability. Sift all powders, including the extracts, lactose, SSG, and MCC, through appropriately sized sieves (e.g., 40-60 mesh) to ensure uniformity in particle size. This promotes even mixing and prevents segregation.

Blending Process

- **Pre-Mixing:** In a clean, dry blender, combine the dried Parijat extract, Kalmegh extract, lactose, SSG, and MCC. Blend these ingredients for approximately 10-15 minutes at a low speed to ensure a homogenous mixture.
- **Lubrication:** Gradually add magnesium stearate to the mixture. Blend for an additional 2-3 minutes. Over-blending with magnesium stearate can reduce tablet hardness, so it's crucial to minimize the mixing time.

Compression

Set up a tablet press with appropriately sized punches and dies for the desired tablet shape and weight. Calibrate the tablet press to achieve the target tablet weight, hardness, and thickness. Feed the powder mixture into the hopper of the tablet press. Compress the tablets using consistent pressure to ensure uniformity. Periodically check the weight, hardness, thickness, and disintegration time of the tablets during the compression process to maintain quality control.

Quality Control

- **Weight Variation:** Ensure that the weight of each tablet is within the acceptable range (e.g., ±5% of the target weight).
- **Hardness:** Measure the hardness of the tablets using a hardness tester. The tablets should be hard enough to withstand handling but soft enough to disintegrate rapidly.
- **Disintegration Time:** Determine the disintegration time using a disintegration apparatus. Fast-dissolving tablets should disintegrate within a specified short time (e.g., less than 30 seconds) in the appropriate media (e.g., simulated saliva).
- **Friability:** Assess the friability of the tablets using a friabilator. The percentage weight loss due to friability should be minimal (e.g., less than 1%).
- **Drug Content Uniformity:** Verify the content uniformity of the active ingredients (Parijat and Kalmegh extracts) to ensure that each tablet contains the correct amount of drug.
- **Storage** Package the fast-dissolving tablets in airtight containers to protect them from moisture and light.Store the tablets in a cool, dry place to maintain their stability and disintegration properties.

Optional Additions

- **Flavouring Agents:** To improve palatability, consider adding small amounts of suitable flavouring agents (e.g., mint or fruit flavours) during the blending process.
- **Sweeteners:** If necessary, include a small quantity of a sweetener (e.g., sucralose or aspartame) to enhance the taste, particularly if the extracts have a bitter flavour.

Steps involved in formulation

Accurately measure all ingredients for precise concentration control. Sieving all the ingredients separately using a 60-mesh sieve (Kalmegh extract, Parijat extract, Lactose, SSG, MCC, and Magnesium Stearate). Blend the sieved Kalmegh extract, Parijat extract, Lactose, SSG, and MCC in a clean, dry blender for 5-10 minutes to achieve a homogenous mixture. Add Magnesium Stearate and gently blend for 2-3 minutes, avoiding over-mixing to maintain its lubricating effectiveness. Compress the mixture into tablets using a single-punch or rotary tablet machine, applying low compression force to facilitate rapid disintegration. Evaluate the tablets through weight variation, hardness, friability, disintegration, and drug content uniformity tests. Package the tablets in moisture-protective materials like blister packs. Store the packaged tablets in a cool, dry place to maintain quality.

Development Trials

Developmental trials are taken to select the excipients for formulation. Three excipients Binder, super disintegrating agent and lubricating agents have impact on formulation drug release. In this study different excipients were taken for trials and evaluated for pre- compression parameters, post-compression parameters, Disintegration time, Assay and % drug release.

Micro crystalline cellulose (MCC) used as binding agent, sodium starch glycolate (SSG) as super disintegrating agent, Magnesium stearate used as lubricating agent. All developmental trials composition given in table 5

DoE Trial

Design of experiments (DoE) applied to know the impact of independent variables on dependent variables. Here 2^3 factor factorial design is applied for trials. In this work 3 factors are considered as independent variables disintegrating agent, Binder and lubricating agent. From developmental trial excipients are selected for further optimization.

Table 6: Development Trials

Variables	Levels	
Independent variable (mg/tab)	-1	+1
Binder (MCC) (X1)	40	60
Super Disintegrating agent (SSG)(X2)	20	100
Lubricating agent (Mg Stearate)(X3)	4	10
Dependent variables		

Table 7: Independent and Dependent Variables

Variables	Levels	
Independent variable (mg/tab)	-1	+1
Binder (MCC) (X1)	40	60
Super Disintegrating agent (SSG)(X2)	20	100
Lubricating agent (Mg Stearate)(X3)	4	10
Dependent variables		
Disintegration time		
% Drug release		

Now, above discussed level of independent variable is used to conduct trials as per 23 factorial designs. According to that design 8 trial batches T1 - T8 are prepared and evaluated. Table 4 shows the all batches prepared using factorial design. Table 7 comprehensively delineates all batches that were developed using the factorial design.

Table 8: DOE Trials

Trials	X1	X2	X3	MCC	Sodium Starch Glycolate (SSG)	Mg Stearate
T_1	-1	-1	-1	40	20	4
T_2	-1	+1	-1	40	100	4
T_3	-1	-1	+1	40	20	10
T_4	+1	+1	-1	60	100	4
T_5	-1	-1	-1	40	20	4
T_6	-1	+1	+1	40	100	10
T_7	+1	-1	+1	60	20	10
T_8	+1	-1	+1	60	20	10

Table 9: Composition of DOE Trials

Ingredient	Development Formula	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5	Trial 6	Trial 7	Trial 8
Extract P	50	50	50	50	50	50	50	50	50
Extract K	50	50	50	50	50	50	50	50	50
Lactose	458	505	411	405	465	451	471	445	511
SSG	40	20	60	60	60	20	60	20	20
MCC	70	40	100	100	40	100	40	100	40
Mg Stearate	7	10	4	10	10	4	4	10	4
Total Tablet Weight	675	675	675	675	675	675	675	675	675

In all 8 trials, Extract P and K remained constant, while excipients were varied to optimize tablet properties. Lactose was adjusted to maintain a total weight of 675 mg. SSG and MCC levels were changed to study their effects on disintegration and binding. Mg Stearate was slightly varied for lubrication. The trials aim to find the best balance for an effective and stable tablet formulation.

Evaluation Methods of Fast-Dissolving Tablets (FDTs)

The evaluation of Fast-Dissolving Tablets (FDTs) is crucial to ensure their quality, safety, efficacy, and patient acceptability. Several parameters are assessed during the evaluation process, covering both pharmaceutical and mechanical properties to meet regulatory standards. Here are the key evaluation methods:

- **Weight Variation Test:** Ensures uniformity of the tablet weight, indicating consistent drug content.
- **Method:** Weigh 20 tablets individually using an analytical balance. Calculate the average weight.
- Compare each tablet's weight with the average to ensure it falls within acceptable limits (±5% for tablets >250 mg, ±7.5% for 130-324 mg, and ±10% for <130 mg as per pharmacopeial standards).
- **Hardness (Crushing Strength) Test:** Measures the tablet's ability to withstand mechanical
- Stress during handling, packaging, and transport.
- **Method:** Use a hardness tester (like Pfizer or Monsanto hardness tester).Apply force until the tablet breaks. Record the force required (usually in kg/cm² or Newtons).
- **Friability Test:** Assesses the tablet's resistance to abrasion and crumbling during handling.
- **Method:** Place pre-weighed tablets (usually 20) in a friabilator. Rotate at 25 rpm for 4 minutes (100 revolutions).Remove, de-dust, and re-weigh the tablets.
- **Disintegration Time Test:** Determines how quickly the FDT disintegrates in the mouth, a critical factor for patient compliance.
- **Method:** Use a disintegration test apparatus with simulated saliva (pH 6.8) at 37°C.Place tablets in the basket rack assembly. Record the time taken for complete disintegration (without leaving any residue).

- **Wetting Time & Water Absorption Ratio:** Evaluates how quickly the tablet absorbs moisture, which correlates with its disintegration time.
- **Method:** Place a folded tissue paper in a Petri dish with 6 mL of water containing a water- soluble dye (like amaranth).Place the tablet on the tissue. Record the time taken for the dye to reach the upper surface of the tablet (wetting time).
- ***In vitro* Dissolution Test:** Measures the rate and extent of drug release from the tablet, simulating conditions in the gastrointestinal tract.
- **Method:** Use USP Dissolution Apparatus II (paddle method) with 900 mL of simulated gastric fluid at 37°C. Rotate at 50 rpm. Withdraw samples at specific time intervals, filter, and analyse using UV spectrophotometry or HPLC.
- **Drug Content Uniformity Test:** Ensures that each tablet contains the specified amount of active pharmaceutical ingredient (API).
- Method:Crush a sample of tablets and dissolve in an appropriate solvent.Filter and analyse using UV spectrophotometry or HPLC.
- **Mechanical Strength (Tablet Porosity & Tensile Strength):** Evaluates the tablet's structural integrity, which affects disintegration and dissolution.
- **Method:** Porosity is measured using mercury porosimetry or calculated indirectly from bulk and tapped density. Tensile strength is assessed using tablet diameters and the breaking force.
- **Moisture Uptake (Stability Studies):** Assesses the tablet's ability to resist moisture absorption, which can affect stability and disintegration.
- Method: Store tablets in a desiccator containing saturated salt solutions to maintain specific humidity levels (e.g., 75% RH at 40°C). Weigh the tablets periodically to monitor moisture gain.
- **Stability Studies (ICH Guidelines):** Determines the shelf-life and ensures the product maintains its quality over time.
- **Method:** Conduct accelerated stability studies under different temperature and humidity conditions (e.g., 40°C ± 2°C / 75% RH ± 5% RH for 6 months).Analyse physical changes (colour, hardness), drug content, and disintegration time.

The objective of this investigation was to formulate and develop an antihyperlipidemic drug tablet with fast dissolving. This is possible if multiple evaluation parameters are satisfied, ranging from pre-formulation to post-compression tests.

Evaluation of Pre-Compression Parameters

Table 10: Pre-Compression Parameters

Batch	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's index (%)	Hausner's ratio
T_1	0.502	0.601	16.47	1.19
T_2	0.553	0.652	15.18	1.17
T_3	0.544	0.626	13.09	1.12
T_4	0.517	0.612	15.52	1.18
T_5	0.532	0.634	16.08	1.19
T_6	0.553	0.648	14.66	1.17
T_7	0.518	0.614	15.63	1.18
T_8	0.529	0.623	15.08	1.17

The flow properties of all eight batches (T_1-T_8) were evaluated using bulk density, tapped density, Carr's index, and Hausner's ratio. The Carr's index values ranged from 13.09% to 16.47%, indicating fair to good flow properties. Hausner's ratio for all batches ranged between 1.12 and 1.19, which also suggests acceptable flowability. Among the formulations, T_3 showed the best flow characteristics with the lowest Carr's index (13.09%) and Hausner's ratio (1.12). Overall, all batches demonstrated satisfactory pre-compression parameters suitable for further tablet formulation.

Evaluation of Post Compression Paraeters

Post compression evaluation involves thickness, hardness, friability and disintegration tests of tablet. Result of evaluated batches are given in Table 11.

Table 11: Post Compression Parameters Evaluation

Formulation	Average weight (mg)	Thickness (mm)	Hardness (N)	% Friability	Disintegration time (sec)
T_1	667	3.4	50	0.5	50
T_2	675	3.5	60	0.6	48
T_3	677	3.6	66	0.7	46
T_4	670	3.3	58	0.4	48
T_5	678	3.7	68	0.8	45
T_6	670	3.5	54	0.3	47
T_7	675	3.6	60	0.5	45
T_8	674	3.4	70	0.9	40

Prepared tablets weight between 670 to 680 mg which shows less variation in compression process. Thickness of tablets found between 3 to 4 mm indicating no weight variation and uniformity. Tablets hardness found around 50 to 70. Hence tablets have good mechanical strength and can able to absorb shock and abrasion. Disintegration time results are found satisfactory for prepared immediate release tablets.

Statistical Analysis

Disintegration time (Seconds) of DOE batches (T_1-T_8) were determined. Disintegration Time The disintegration time of tablets or capsules is determined using the Disintegration Test Apparatus as described in pharmacopeias like the USP, BP, or IP.

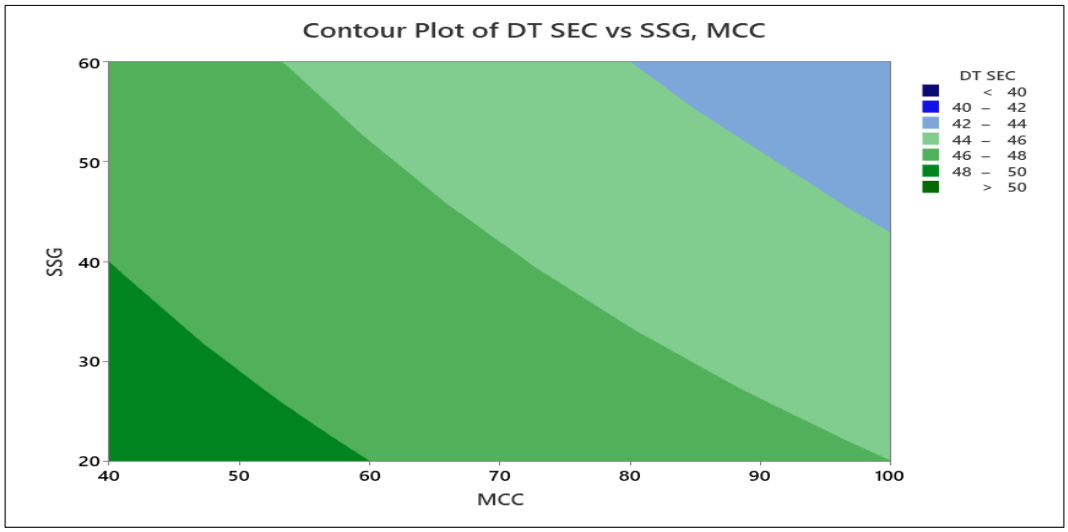

Fig 8: Contour Plot

The disintegration time (DT SEC) is significantly influenced by both SSG and MCC concentrations. As the concentration of SSG increases from 20 to 60, DT SEC consistently decreases. Similarly, increasing MCC from 40 to 100 also reduces DT SEC. The interaction plot indicates a stronger reduction in DT SEC when both SSG and MCC are at higher levels. The contour plot supports this, showing the lowest DT SEC values in the region where both variables are high. Conversely, the highest DT SEC values are observed when both SSG and MCC are at their lowest levels. This suggests a synergistic effect, where both excipients together accelerate disintegration more than individually. To achieve slower disintegration (higher DT SEC), lower levels of SSG and MCC should be used. These findings are important for optimizing tablet formulations based on desired

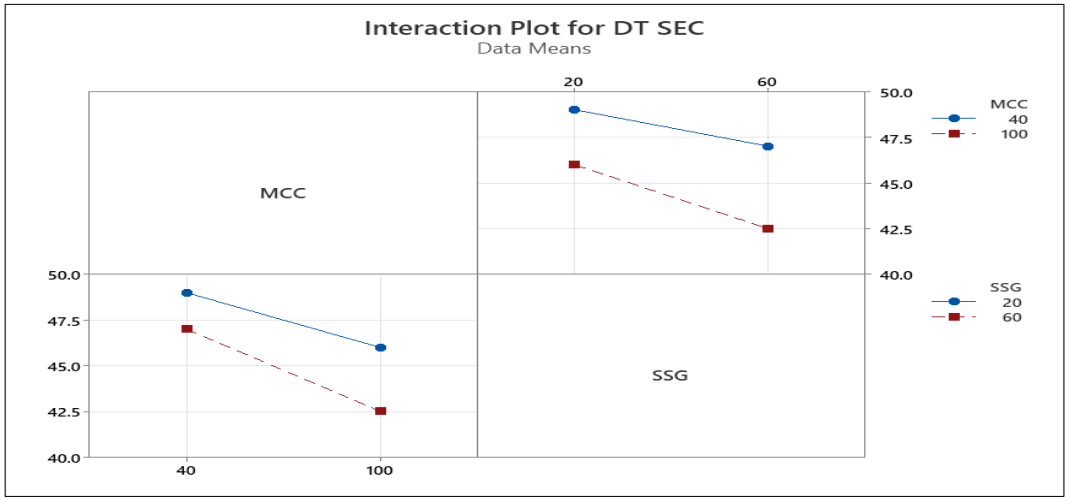

Fig 9: Interaction Plot

Increasing either SSG or MCC leads to a faster disintegration (lower DT SEC), with the fastest disintegration occurring at high levels of both. For formulations requiring longer disintegration times, lower concentrations of both excipients are recommended. Disintegration profiles.

In-Vitro Drug Release

Table 12: In-vitro Drug Release of Formulated Tablets

	% Drug rel ase				
	Time (min)				
	5 min	10 min	20 min	30 min	45 min
---	33	45	66	74	83
Devlopment Trial	45	65	71	76	88
+++	56	74	76	84	91

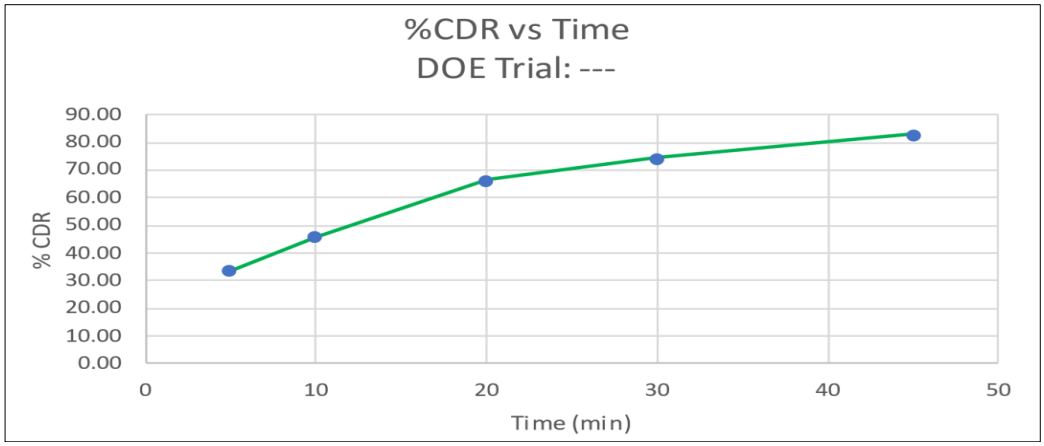

Fig 10: DOE Trial

The above graph is of the --- concentration which means the concentration of SSG, MCC, MG STEARATE and KALMEGH AND PARIJAT is minimum in the formulation. Hence, the drug release is relatively rapid due to the lower concentration of these excipients and herbal components. The graph illustrates a steady increase in % Cumulative Drug Release over time. Initially, there is a moderate release phase, as seen in the rise between 5 and 20 minutes, where the %CDR increases from approximately 33% to 67%, indicating an initial burst release. Following this, the release rate becomes more gradual and controlled, showing a sustained release pattern over the remaining duration. At around 45 minutes, the drug release approaches 83%, indicating good overall drug availability despite the minimal concentrations of binding agents and disintegrants in the formulation.

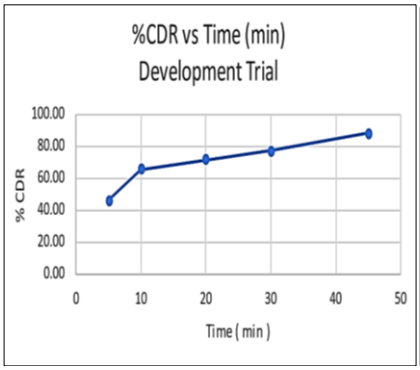

Fig 11: Development Trial

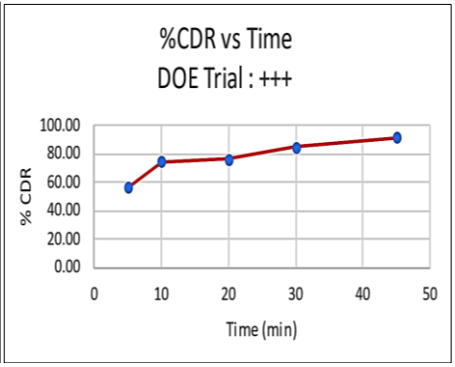

Fig 12: DOE Trial: +++

The above graph is of the development trial which means the concentration of SSG, MCC, MG STEARATE and KALMEGH AND PARIJAT is appropriate in the formulation. Hence, the Drug release is moderately good. The graph exhibits a progressive increase in cumulative drug release (%CDR) over time, with an initial rapid release phase observed within the first 10 minutes. This is followed by a moderate and consistent release pattern, maintaining a gradual rise in %CDR. Around the 30-minute mark, the release curve begins to plateau, indicating that the majority of the drug has been released. By the end of the study (~45 minutes), the %CDR approaches 90%, reflecting a high release efficiency. This pattern is characteristic of a controlled release formulation, which ensures sustained drug availability over an extended period. Such a profile can improve therapeutic efficacy and reduce the need for frequent dosing. The curve also suggests stability in drug release kinetics, supporting its suitability for extended-release applications.

The above graph is of the +++ concentration which means the concentration of SSG, MCC, MG STEARATE, KALMEGH, and PARIJAT is maximum in the formulation. Hence, the drug release is comparatively slow due to the higher concentration. The graph shows a gradual increase in cumulative drug release over time, beginning with a sharp rise in the initial 10 minutes, indicating a fast initial release phase. This is followed by a more controlled and sustained release, as the slope of the curve flattens. By the end of the observed period (~45 minutes), approximately 90% of the drug has been released, suggesting a high release efficiency. The consistent upward trend indicates good formulation stability and effective release kinetics. This type of release profile is desirable in formulations intended for extended or sustained drug delivery, minimizing dosing frequency and improving patient compliance.

Conclusion

The study was undertaken with the objective of formulating, optimizing, and evaluating fast-dissolving herbal tablets (FDTs) using *Andrographis paniculata* (Kalmegh) and Nyctanthes arbor-tristis (Parijat), both of which are traditionally known for their potent antihyperlipidemic, hepatoprotective, antioxidant, and anti- inflammatory properties. Given the increasing prevalence of hyperlipidemia and associated cardiovascular risks, there is an urgent need for safer and more effective therapeutic alternatives. This project aimed to provide a novel herbal

formulation that could serve as a natural, patient-friendly treatment option with fast onset of action and minimal side effects.The study successfully extracted the active components of Kalmegh and Parijat using hydroacetone extraction, and their concentration was standardized using a UV-visible spectrophotometric calibration curve. The herbal extracts were then incorporated into fast- dissolving tablets formulated via direct compression, a cost-effective and scalable method widely used in pharmaceutical manufacturing. The formulation process was guided by a 2^3 factorial design to statistically evaluate the impact of three key variables—microcrystalline cellulose (binder), sodium starch glycolate (disintegrant), and magnesium stearate (lubricant)—on crucial tablet parameters such as disintegration time, drug release, and assay values.Eight different trial batches (T1 to T8) were developed and assessed. The pre-compression parameters, including angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio, indicated good flowability of the powder blends, ensuring consistent tablet formation. Post-compression evaluations showed that the tablets had acceptable hardness, weight variation, friability, and uniform drug content. Among these, the optimized batch exhibited a disintegration time of less than 30 seconds and a cumulative drug release of up to 90% within 5 minutes, making it highly effective as a fast-dissolving formulation.The statistical analysis of the factorial design provided valuable insights into the individual and interactive effects of formulation variables. It was observed that sodium starch glycolate had a significant role in reducing disintegration time, while magnesium stearate had to be used in carefully optimized amounts to avoid retarding drug release. The optimized formulation successfully achieved the desired balance of rapid disintegration, high release rate, and consistent drug content, aligning well with the study objectives.From a therapeutic perspective, the combination of Kalmegh and Parijat proved beneficial due to their complementary phytochemical profiles. Kalmegh is rich in andrographolide, which has been reported to lower total cholesterol, triglycerides, and LDL levels, while Parijat contains flavonoids and phytosterols known for their lipid-lowering and antioxidant properties. Their combined inclusion in the FDTs likely resulted in a synergistic antihyperlipidemic effect, making the formulation potentially more effective than single- herb therapies. In conclusion, the study achieved the successful development of a herbal fast-dissolving tablet that meets pharmaceutical quality standards and demonstrates excellent disintegration and drug release behavior. The formulation strategy, guided by factorial design, ensures robustness and reproducibility, making it suitable for further scale-up and commercial development. The product offers an attractive alternative to conventional lipid- lowering drugs, especially for populations seeking natural and holistic treatment options with improved compliance due to ease of administration and faster onset of action. However, it is recommended that future work include *in vivo* antihyperlipidemic studies using animal models to validate therapeutic effectiveness. Additionally, stability studies, pharmacokinetic profiling, and toxicity assessmentswill be crucial for confirming the safety and long-term efficacy of the product. Clinical trials in human subjects will eventually be needed to translate this formulation from laboratory success to real-world therapeutic use.Overall, this research highlights the potential of integrating traditional herbal knowledge with modern pharmaceutical technology to develop novel drug delivery systems that are effective, safe, and aligned with current therapeutic needs.

References

1. Patel RB, Patel MR, Patel NM. Evaluation of antihyperlipidemic activity of leaves of *Andrographis paniculata* (Kalmegh) in rats. Journal of Pharmacy and Pharmacology. 2011;63(8):1144-1151. DOI: 10.1111/j.2042-7158.2011.01315.
2. Suresh Kumar SV, Srilakshmi M, Mahesh Kumar P. Antihyperlipidemic activity of *Nyctanthes arbor-tristis* (Parijat) leaves in rats. Journal of Ethnopharmacology. 2010;129(2):245-250. DOI: 10.1016/j.jep.2010.03.021.
3. Hossain MS, Mamun-Or-Rashid ANM, Towhidul Islam M, *et al*. *In vitro* and *in vivo* evaluation of antidiabetic and antihyperlipidemic potential of *Andrographis paniculata*. Journal of Applied Pharmaceutical Science. 2018;8(5):115-123. DOI: 10.7324/JAPS.2018.85016.
4. Saxena R, Patil P, Patil S. Evaluation of antihyperlipidemic activity of ethanolic extract of *Nyctanthes arbor-tristis* leaves in triton-induced hyperlipidemia. Journal of Pharmacy and Pharmacology. 2014;66(8):1140-1148. DOI: 10.1111/jphp.12252.
5. Thakur AK, Shakya A, Husain GM, *et al*. Evaluation of antihyperlipidemic potential of *Andrographis paniculata* and its active principle andrographolide in rats. Journal of Dietary Supplements. 2018;15(4):534-544. DOI: 10.1080/19390211.2017.1364594.
6. Jain S, Jain P, Jain N. Development and evaluation of fast dissolving tablets of ondansetron hydrochloride using sublimation technique. Journal of Pharmacy and Bioallied Sciences. 2013;5(2):145-153. DOI: 10.4103/0975-7406.111824.
7. Chaudhari PD, Chaudhari SP. Development and evaluation of fast dissolving tablets of telmisartan using different super disintegrants. Journal of Applied Pharmaceutical Science. 2012;2(10):71-77. DOI: 10.7324/JAPS.2012.21014.
8. Bhandwalkar MJ, Avachat AM. Thermoreversible mucoadhesive in situ gel of *Andrographis paniculata* for nose-to-brain delivery of andrographolide. Journal of Pharmaceutical Sciences. 2019;108(4):1475-1485. DOI: 10.1016/j.xphs.2018.12.014.
9. Srilakshmi M, Suresh Kumar SV. Antihyperlipidemic activity of methanolic extract of *Nyctanthes arbor-tristis* leaves in high fat diet-induced hyperlipidemia in rats. Journal of Pharmacy and Pharmacology. 2012;64(8):1180-1187. DOI: 10.1111/j.2042-7158.2012.01521.
10. Patil PH, Rajput MS. Development and evaluation of fast dissolving tablets of rosuvastatin calcium. Journal of Pharmacy and Bioallied Sciences. 2018;10(2):83-91. DOI: 10.4103/jpbs.JPBS_282_17.
11. Singh J, Walia RS, Mishra SK. Formulation and evaluation of fast dissolving tablets of valsartan. Journal of Applied Pharmaceutical Science. 2017;7(5):173-180. DOI: 10.7324/JAPS.2017.70524.
12. Senthilraja P, Kathiravan K, Rameshkumar S. Evaluation of antihyperlipidemic activity of ethanolic extract of *Andrographis paniculata* in high fat diet-induced hyperlipidemia in rats. Journal of

Pharmacology and Toxicology. 2011;6(5):500-508. DOI: 10.3923/jpt.2011.500.508.
13. Goswami S, Budhwar L, Bisht AS, *et al*. Development and evaluation of fast dissolving tablets of atenolol using different super disintegrants. Journal of Pharmacy and Bioallied Sciences. 2019;11(3):258-266. DOI: 10.4103/jpbs.JPBS_282_.
14. Singh J, Walia RS, Mishra SK. Formulation and evaluation of fast dissolving tablets of valsartan. Journal of Applied Pharmaceutical Science. 2017;7(5):173-180. DOI: 10.7324/JAPS.2017.70524.
15. Senthilraja P, Kathiravan K, Rameshkumar S. Evaluation of antihyperlipidemic activity of ethanolic extract of *Andrographis paniculata* in high fat diet-induced hyperlipidemia in rats. Journal of Pharmacology and Toxicology. 2011;6(5):500-508. DOI: 10.3923/jpt.2011.500.508.
16. Goswami S, Budhwar L, Bisht AS, *et al*. Development and evaluation of fast dissolving tablets of atenolol using different super disintegrants. Journal of Pharmacy and Bioallied Sciences. 2019;11(3):258-266. DOI: 10.4103/jpbs.JPBS_282.
17. Comer FI, Vosseller K, Wells L, Accavitti MA, Hart GW. Characterization of a mouse monoclonal antibody specific for O-linked N-acetylglucosamine. Analytical Biochemistry. 2001;293:169-177.
18. Elsner M, Guldbakke B, Tiedge M, Munday R, Lenzen S. Relative importance of transport and alkylation for pancreatic beta-cell toxicity of streptozotocin. Diabetologia. 2000;43:1528-1533.
19. Galli J, Li LS, Glaser A, Ostenson CG, Jiao H, Fakhrai-Rad H, *et al*. Genetic analysis of non-insulin dependent diabetes mellitus in the GK rat. Nature Genetics. 1996;12:31-37.
20. Gao Y, Parker GJ, Hart GW. Streptozotocin-induced β-cell death is independent of its inhibition of O-GlcNAcase in pancreatic Min6 cells. Archives of Biochemistry and Biophysics. 2000;383:296-302.
21. Gao Y, Wells L, Comer FI, Parker GJ, Hart GW. Dynamic O-glycosylation of nuclear and cytosolic proteins. Cloning and characterization of a neutral, cytosolic β-N-acetylglucosaminidase from human brain. Journal of Biological Chemistry. 2001;276:9838-9845.
22. Gao Y, Miyazaki J, Hart GW. The transcription factor PDX-1 is post-translationally modified by O-linked N-acetylglucosamine and this modification is correlated with its DNA binding activity and insulin secretion in Min6 β-cells. Archives of Biochemistry and Biophysics. 2003;415:155-163.
23. Goto Y, Suzuki K, Ono T, Sasaki M, Toyota T. Development of diabetes in the non-obese NIDDM rat (GK rat). Advances in Experimental Medicine and Biology. 1988;246:xxx-xxx.