

NOVEL HERBAL TRANSDERMAL PATCHES OF SARACA ASOKA FOR EFFECTIVE
MANAGEMENT OF DYSMENOREA

Mrs. V.ASHLIN VIJI., M.Pharm.

AISWARIYA.R

DHANYA.DM

JENISHA.S

NANDHANA.W

SATHEESWARN.P

THENKARAI MAHARAJAN.K

Prof.Dr. J. JASLIN EDWARD,

M.Pharm., Ph.D

Mrs. T.JAGHATHA., M.Pharm

Abstract

Dysmenorrhea is a prevalent gynecological disorder causing painful uterine cramps that significantly impair women's quality of life. Conventional treatments like NSAIDs cause gastrointestinal and cardiovascular adverse effects with long-term use. The present study aimed to formulate and evaluate a novel herbal transdermal patch of *Saraca asoka* bark extract, rich in flavonoids, tannins, and glycosides with proven anti-inflammatory, analgesic, and uterotonic properties. Bark extract was prepared by maceration using methanol and incorporated into an HPMC-based polymer matrix. Formulated patches were evaluated for thickness, weight variation, folding endurance, tensile strength, surface pH, moisture content, and drug content uniformity — all within acceptable limits. Stability studies over three months confirmed drug content retention above 94%. The developed herbal transdermal patch offers a non-invasive, patient-compliant, and effective alternative for dysmenorrhea management, successfully integrating traditional Ayurvedic medicine with modern drug delivery technology.

Introduction

Dysmenorrhea is a frequently occurring gynecological condition seen among adolescent girls and women of reproductive age. It is mainly characterized by painful menstrual cramps experienced before or during menstruation. Along with abdominal pain, women may also experience symptoms such as nausea, headache, fatigue, vomiting, lower back pain, and emotional disturbances. Severe menstrual pain can interfere with daily life, reduce concentration, disturb emotional health, and negatively affect academic and professional performance. In many cases, dysmenorrhea results in absenteeism from schools and workplaces, thereby affecting overall quality of life and productivity.

Clinical importance

[Dysmenorrhea is generally divided into two categories: primary dysmenorrhea and secondary dysmenorrhea. Primary dysmenorrhea occurs in the absence of any pelvic disease and is mainly associated with increased synthesis of prostaglandins, which cause strong uterine contractions and decreased uterine blood circulation. Secondary dysmenorrhea develops due to underlying gynecological conditions such as endometriosis, uterine fibroids, adenomyosis, or pelvic inflammatory disease. Primary dysmenorrhea is more common among adolescents and young women and usually appears a few years after menarche. The condition commonly presents with cramping pain in the lower abdomen that may spread to the back and thighs, accompanied by nausea, diarrhea, dizziness, and tiredness. Lifestyle-related factors including stress, lack of physical activity, obesity, smoking, and hereditary predisposition can worsen the symptoms. Although nonsteroidal anti-inflammatory drugs (NSAIDs) and hormonal therapies are widely used for treatment, prolonged use may lead to side effects such as gastric irritation, hormonal disturbances, cardiovascular risks, and poor adherence among patients.

Important of herbal medicine

In recent years, herbal medicines have received considerable interest due to their natural origin, cost-effectiveness, safety, and therapeutic benefits. Traditional medicinal systems like Ayurveda and Siddha have extensively used medicinal plants for the treatment of menstrual and reproductive disorders in women. Medicinal herbs contain several phytoconstituents, including flavonoids, alkaloids, tannins, glycosides, and phenolic compounds, which exhibit analgesic, antioxidant, anti-inflammatory, and antispasmodic properties. Among these medicinal plants, *Saraca asoka* holds a significant place in the management of gynecological disorders. The bark of *Saraca asoka* has traditionally been used in Ayurvedic formulations for conditions such as dysmenorrhea, menorrhagia, leucorrhea, and uterine weakness. Owing to its therapeutic potential and traditional importance, *Saraca asoka* is considered a valuable herbal source for the development of advanced pharmaceutical formulations aimed at women's reproductive health.

Saraca asoka

Saraca asoka, widely known as the Ashoka tree, is an evergreen medicinal plant belonging to the Fabaceae family. It is predominantly found in India and other Southeast Asian regions and holds great importance in traditional medicine, culture, and mythology. Ancient Ayurvedic texts describe its extensive use in the treatment of various female reproductive disorders. Among different parts of the plant, the bark is considered highly medicinal due to the presence of several bioactive constituents such as flavonoids, tannins, glycosides, saponins, and polyphenolic compounds. Research studies have reported that *Saraca asoka* exhibits analgesic, antioxidant, anti-inflammatory, antimicrobial, and uterine-supportive activities. These pharmacological effects play an important role in reducing menstrual pain and discomfort. The active constituents present in the bark may help decrease inflammation and suppress excessive uterine contractions caused by prostaglandins, thereby providing relief from symptoms associated with dysmenorrhea.

Transdermal drug delivery systems

Herbal transdermal patches represent a combination of traditional herbal therapy and modern drug delivery technology. These formulations are designed to enhance therapeutic effectiveness while minimizing unwanted systemic side effects. By providing controlled and sustained release of active phytoconstituents, transdermal patches help maintain consistent drug levels in the body over an extended period and reduce the need for repeated dosing. In contrast to oral herbal preparations, transdermal delivery avoids gastrointestinal degradation and hepatic first-pass metabolism, thereby improving the bioavailability of herbal constituents. Such systems may also reduce gastric irritation that is often associated with long-term oral use of analgesic medications. Furthermore, herbal transdermal patches are non-invasive, simple to apply, and more convenient for patients, making them particularly suitable for long-term conditions like dysmenorrhea.

Advance of herbal transdermal patches

Even though *Saraca asoka* has been traditionally utilized for the treatment of various gynecological disorders, only limited research has explored its application in transdermal patch formulations for the management of menstrual pain. Hence, the present study is focused on the formulation and evaluation of a herbal transdermal patch containing *Saraca asoka* extract for the effective treatment of dysmenorrhea. The proposed formulation is expected to offer prolonged analgesic and anti-inflammatory activity, better bioavailability, enhanced patient compliance, and fewer adverse effects when compared with conventional oral medications. In addition, this research highlights the potential of integrating traditional herbal remedies with advanced pharmaceutical approaches for the development of safer and more effective drug delivery systems.

PLANT AND EXCIPIENT PROFILE

Source

Natural sources:

It is distributed in evergreen forests of India up to an elevation of about 750 meters. It is found throughout India. Specially in Himalaya, Kerala, Bengal and whole south region. In Himalaya it is found at Khasi, Garo and Lussi hills and in Kerala region it is found in Patagiri, Kaikatty & Pothundi of Palakkad district, Thrisur, Kollam and Kannaur districts.

Cultivated sources:

It is widely cultivated in botanical garden, herbal garden

Pharmaceutical sources:

Ayurvedic pharmacies, extract suppliers.

Botanical Synonyms:

Saraca indica L

Jonesia asoka roxb

Saraca bijuga prain

Route of Administration

Oral (capsules, tablets, powders)

Topical formulations

Therapeutic Properties of saraca asoka:

Uterine Tonic

Anti-menorrhagic

Anti-dysmenorrheal

Estrogenic activity

Anti-inflammatory

Anti-microbial

Astringent

Antioxidant

Safety and toxicity:

Saraca asoka is generally considered safe when used in recommended doses and is well tolerated in oral forms like decoction, powders and syrups. Adverse effect are rare but may include mild gastrointestinal upset or occasional allergic reactions .it is cautioned early in pregnancy due to its uterotonic effects and limited safety data during lactation. Acute and chronic toxicity studies suggest low toxicity, with no major harmful effect reported in traditional use.¹

Uses:

Gynecological disorders

Anti-inflammatory Agent

Astringent uses**Anti microbial activity****Other traditional uses**

Treats leucorrhea (vaginal discharge)

Used as cardio-protective and liver protective agent in some formulations

Excipient profile**HPMC (Hydroxypropyl Methylcellulose):**

Hydroxypropyl Methylcellulose (HPMC), also known as hypromellose, is a semi-synthetic, non-ionic cellulose ether derived from natural cellulose obtained from wood pulp or cotton linters. It is produced by chemically modifying cellulose through partial substitution of its hydroxyl groups with methoxy and hydroxypropoxy groups, which improve its solubility and functional properties. HPMC is widely used in the pharmaceutical industry because of its excellent film-forming ability, thickening property, biocompatibility, and controlled drug release characteristics. It is an inert, non-toxic, and stable polymer that dissolves in cold water to form a clear, viscous solution and exhibits thermal gelation upon heating. Due to its versatility, safety, and compatibility with many active pharmaceutical ingredients, HPMC plays a significant role as a binder, coating agent, matrix-forming agent, and viscosity enhancer in various dosage forms.

Propylene glycol:

Propylene glycol (PG) is a **clear, colorless, and nearly odorless hygroscopic liquid** that belongs to the class of dihydric alcohols (diols), with the chemical formula $C_3H_8O_2$. It is widely used in the pharmaceutical, food, cosmetic, and industrial industries due to its **excellent solvent properties, low toxicity, and miscibility with water and many organic solvents**. In pharmaceuticals, propylene glycol serves as a **solvent, humectant, preservative, and carrier** for both oral and topical formulations. It enhances the solubility and bioavailability of poorly water-soluble drugs, stabilizes formulations, and improves moisture retention in creams, lotions, and injectables. Propylene glycol is considered **generally recognized as safe (GRAS)** by regulatory

authorities when used within recommended limits, making it a highly versatile excipient in modern drug formulations.

Glycerin

Glycerin, also known as **glycerol**, is a **colorless, odorless, sweet-tasting, viscous liquid** that belongs to the class of **trihydroxy alcohols (triols)** with the chemical formula $C_3H_8O_3$. It is a naturally occurring compound found in **animal fats and vegetable oils** as part of triglycerides, and it can also be produced synthetically by the hydrolysis of fats or chemical synthesis. Glycerin is **hygroscopic**, highly soluble in water, and chemically stable under normal conditions. In the pharmaceutical industry, it is widely used as a **humectant, solvent, sweetening agent, emollient, and lubricant** in oral, topical, and parenteral formulations. Its **non-toxic, biocompatible, and moisturizing properties** make it an essential excipient in a wide range of dosage forms, including syrups, creams, ointments, suppositories, and injectables.

Preformulations studies

Preformulation testing is the first step in the rational development of dosage forms of drug substance. It can be defined as an investigation of physical and chemical properties of a drug substance alone and when combined with excipients. The overall objective of preformulation testing is to generate information useful to the formulator in developing stable and bioavailable dosage forms that can be manufactured.

The following Preformulation studies are carried out

Finding the absorption maxima

Physical appearance.

Solubility

Melting point

Identification test²

Collection of plant

a. Collection of plant material

The bark of *Saraca asoca* was collected from nearby Colachel area, Kanyakumari district (PIN: 629251), Tamil Nadu during November 2025. The collected plant material was cleaned to remove adhering dirt and shade dried for further processing.

b. Identification and authentication of plant material

The collected bark specimen was botanically identified and authenticated by the Department of Botany, Women's Christian College, Nagercoil, Kanyakumari District, Tamil Nadu – 629001. The plant was confirmed as *Saraca asoca* (Roxb.) Willd., belonging to the family Leguminosae, and the authentication certificate is provided. The samples were identified as *saraca asoka* belongs to the family Leguminosae.

Extraction of saraca asoka bark

Saraca asoka plant was collected . *Saraca asoka* bark was collected then shade dried to preserve its active constituents. The dried bark was then finely powdered using a mechanical grinder. About 100 g of the powdered bark was accurately weighed and taken in a clean, dry container.

To the powdered drug, 500 ml of 70% ethanol was added as the extraction solvent. The mixture was stirred thoroughly to ensure proper mixing and to facilitate the penetration of solvent into the plant material for efficient extraction.

The container was tightly closed and kept aside for 48 hours at room temperature for maceration. During this period, the mixture was occasionally stirred to enhance the extraction of phytoconstituents into the solvent.

After 48 hours, the mixture was filtered by Whatman filter paper to obtain a clear filtrate. The residue was pressed well to recover the maximum amount of extract.

The filtrate obtained was then concentrated using a water bath by evaporating the solvent under controlled temperature. The process was continued until a thick extract was formed, which was further dried to obtain a powdered extract. The final extract was stored in an airtight container for further use.³

Finding the absorption maxima (λ max):

The absorption maxima were found for identification of drug. Ultraviolet Visible spectrophotometry has been used to obtain specific information on the chromophoric part of the molecules. Organic molecules in solutions when exposed to light in the Visible/Ultraviolet region of the spectrum absorb light of particular wavelength depending on the type of electronic transition associated with the absorption.

The drug solution (5, 10, 15, 20, 25 ug/ml) in distilled water was taken in a standard cuvette and scanned in the range of 280 nm in UV spectrophotometer.⁴

Physical appearance

Colour

A small quantity of saraca asoka was taken in a test tube and viewed in well illuminated place.

Taste and odour

Very less quantity of saraca asoka was used to get taste with help of tongue as well as smelled to get the odour.⁵

Solubility

The spontaneous interaction of two or more substance to form a homogeneous molecular dispersion is called as solubility.

The solubility of saraca asoka was studied in various solvents. Saraca asoka (10mg) was suspended separately in a 10 ml of different solvents at room temperature in tightly closed test tubes and shaken on wrist action.⁵ The solubility profiles of saraca asoka in various solvents are shown in the table:

The approximate solubility of substances are indicated by the terms in the accompanying table:

Standard solubility profile

Standard solubility profile

Descriptive term	Parts of solvent required for 1 part of solute
-------------------------	---

Very soluble	Less than 1
Freely soluble	From 1 to 10
Soluble	From 10 to 30
Sparingly soluble	From 30 to 100
Very slightly soluble	From 1000 to 10,000
Practically insoluble (or) insoluble	Greater than or equal to 10,000

Preparation of Standard curve of saraca asoka:

Accurately weighed quantity of saraca asoka (100mg) was dissolved in ethanol and made up to 100ml (1000mcg/ ml) with phosphate buffer pH7.4. Each ml of stock solution contains 1mg of saraca asoka. From this stock solution, 10ml was taken and made up to 100ml (100mcg/ml). Then the absorbance was measured spectrophotometrically at 280 nm using phosphate buffer as blank. The standard plot was drawn with concentration (mcg/ml) in x-axis and absorbance at 280nm in y-axis.

Preparation of patches of saraca asoka:

Saraca asoka patches was prepared by solvent casting method. The film was prepared in a petriplate had a diameter of 7.6 cm with 6ml capacity. The composition of polymer keeping the total 400mg in the patches. The polymeric solutions were prepared using water. The polymeric solution was added to the drug saraca asoka. Then plasticizer and glycerin were mixed and stirred well to get a homogenous solution. The resulted uniform solution was casted on the mould and air dried for 24 hours. After 24 hrs the dried films were taken out and stored in desiccators for further studies.⁶ the result is shown in table:6.4

6.10 Compatibility studies: (FTIR)

This study was performed using FTIR spectrophotometer and the spectrum was recorded in the region of 4000 to 400 cm⁻¹. This study was carried to confirm the compatibility between

drug and the excipients used for the transdermal patches and identify the possible interactions. In this study, FTIR Spectra for the extract & physical mixture of extract along with the excipients were obtained. The baseline correction was done using dried KBr. The procedure consisted of dispersing a sample in KBr (1:1 ratio) and then it is compressed into discs by the application of pressure of 5 tons for 5 minutes in a hydraulic press. The pellet was then placed carefully in the light path and the spectrum was recorded from 4000 to 400 cm^{-1} .⁷

6.11 Optimization

Before obtaining the appropriate formulation, various trial were made with respect to solvent, plasticizer and polymer concentration to get a patches patches having good film characteristics like uniform thickness, uniform weight, homogenous drug dispersion and optimum tensile strength. The obtained strip was visually compared with a commercially available transdermal patches.⁵

When the amount of polymer is less than 0.4g or greater than 0.4g the folding endurance of the patches was affected. If the quantity was less than 0.4g, handling of the patches will affected and if it is greater than 0.4g, the patches become thick or break with insignificant tensile strength. 0.05ml of glycerine was added as plasticizer and to produce flexible patches without having major influence on their release property.

Optimization of drug and polymer

S. NO	INGREDIENTS	P ₁	P ₂	P ₃	P ₄	P ₅
1.	Saraca asoka (g)	0.1	0.05	0.05	0.04	0.03
2.	Polymer (HPMC) (g)	0.6	0.4	0.5	0.4	0.3
3.	Water (ml)	7	5	5	5	5

4.	Propylene glycol (ml)	1	1	1	1	1
5.	glycerine	0.15	0.15	0.15	0.15	0.15

Trial patches p1**Trial patches p2**



Trial patches p3

Physicochemical evaluation of saraca asoka transdermal patches:

Formulated films were subjected to the preliminary evaluation tests. Films with any imperfections, entrapped air, or differing in thickness, weight (or) content uniformity were excluded from further studies.

Uniformity of weight

This was done by weighing five different patches of individual batch taking the uniform size at random and calculating the average weight of three. The tests were performed on patches which was dried at 60°C for 4 hrs prior to testing.

Thickness of the patches

The thickness of the patches was assessed by using digital vernier caliper at different points of the patch. From each formulation three randomly selected strips were used. The average value for thickness of a single strip was determined.

Folding Endurance

This was determined by repeatedly folding one patches at the same place till it broke. The number of times the patches could be folded at the same place without breaking gave the value of folding endurance.

Percentage Moisture uptake

The strip of saraca asoka were weighed accurately and placed in desiccators containing aluminium chloride. After 24hrs, the patches were taken out and weighed. The percentage moisture uptake was calculated as the difference between final and initial weight. With respect to initial weight. It is calculated by using following formula.

Percentage Moisture Content

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

Percentage Moisture content

The patches were weighed and kept in desiccators containing calcium chloride. After 24hrs the patches were taken out and weighed. The percentage moisture content was calculated using the following formula.

Percentage moisture content

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

Determination of surface pH

The patches were allowed to swell by keeping them in contact with 1 ml of distilled water for 2 h at room temperature and pH was noted down by bringing the electrode in contact with the surface of the patches, allowing it to equilibrate for 1 min.

Percent Elongation

When stress is applied, a patch sample stretches and this is referred to as strain. Strain is basically the deformation of strip divided by original dimension of the sample. Generally elongation of patches increases as the plasticizer content increases. It is calculated by using following formula.

Percentage elongation

$$= \frac{\text{Increase in length of patches}}{\text{Initial length of patches}} \times 100$$

Tensile strength

Tensile strength is the maximum stress applied to a point at which the patches specimen breaks. It is calculated by the applied load at rupture divided by the cross-sectional area of the patches as given in the equation below:

Percentage elongation

$$= \frac{\text{Load at failure}}{\text{patches thickness} \times \text{strip width}} \times 100$$

Cellophane Membrane Treatment

Cellophane membrane was boiled in the distilled water for 1 hr and washed with fresh distilled water for three times and kept in ethanol for 24 hrs. It was washed with distilled water and treated with 0.3% sodium sulphite and soaked in distilled water for 2min at 60°C followed by

acidified with 0.2% sulphuric acid. Finally the membrane was dipped in boric buffer (pH 9) till it is used for permeation study.

Drug Permeation Studies

The in vitro release rate of *saraca asoka* patches were evaluated by open ended tube through using PB pH 7.4 as diffusion medium up to 12 hours studies. The cellophane membrane is tied in one end of the tube and then immersed in the receptor compartment containing 400ml of PB pH7.4. Which was stirred at medium speed and maintained at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$. Samples were withdrawn at regular time intervals and the same volume was replaced by fresh diffusion medium. The samples were analyzed using UV - visible spectrophotometer (ShimadzuUV1700) set at 280 nm.⁸

Release Kinetics

Data obtained from invitro release studies were fitted to various kinetic equations. The kinetic models used are zero order equations ($Q=k_0t$), First order equation ($\ln(100 - Q) = \ln Q - k_1t$), Higuchi equation ($Q=kt^{1/2}$), Hixson and crowell model $Q^{1/3} \propto V^{1/3}$ and $Q^{2/3} \propto V^{2/3}$ - Modified root cube equation. Further, to find out the mechanism of drug release, first 60% drug release was fitted in Kormeyer and Peppas equation ($Q=k_p t^n$). Where, Q is the percent of the drug release at time t and k_0 and k_1 are the coefficients of the equations and 'n' are the release exponent. The 'n' value is used to characterize different release mechanism. The order of drug release can be assessed by graphical treatment of drug release data.

A plot of cumulative % drug release versus time would be linear if the drug release follows zero order (i.e. Concentration independent release).

A plot of log of % remaining drug versus time would be linear, if the drug release follows first order (i.e. Concentration dependent release)

The linear equation for zero order drug release plot is:

$$C_t = C_0 - Kt$$

Where,

C_t = concentration remaining at time t,

C_0 = original concentration,

t = time,

k = release rate

The linear equation for first order release plot is

$$\log C_0 K t$$

$$\log C = \frac{\log C_0 K t}{2.303}$$

$$2.303$$

A matrix device as the name implies, consists of drug dispersed homogeneously throughout a polymer matrix.

In this model, drug in the outside layer exposed to the bathing solution is dissolved first and then diffuses out of the matrix. This process continues with the interface between the bathing solution and the solid drug moving towards the interior. Obviously, for this system to be diffusion controlled, the rate of dissolution of drug particles within the matrix must be much faster than the diffusion rate of dissolved drug leaving the matrix.

Hydrophilic matrix tablets contain a water swellable polymer. On contact with gastric juices the tablet surface gels, impeding further liquid penetration into the tablet core and providing a rate controlling layer. Dissolution occurs at the gel core interface and drug diffuse out through the gelled layer.

Drug release is controlled by penetration of water through a gel layer produced by hydration of the polymer and diffusion of drug through the swollen, hydrated matrix, in addition to erosion. The extent to which diffusion or erosion controls release depends on the polymerration.

Mechanism of release from erodible matrix has been described by Hopfenberg. A simple expression describing release from erodible is

$$[1 - M_t / M]^3 = 1 - kt$$

Where,

M_t = mass of drug release at time,

M = mass release at the infinite time,

K = rate of erosion,

T = time

Thus a plot of $[1 - M_t / M]$ versus the time will be linear. If the release of drug from the matrix is erosion controlled.

In order to ascertain whether the drug release occurs by diffusion or erosion, the drug release data was subjected to following modes of data treatments.

1) Amount of drug release versus square root of time (Higuchi Plot).

2) $[1 - M_t / M]^3$ versus time.

Accelerated stability studies:

Stability

Stability is official defined as the time lapse during which the drug product retains the same property and characteristics that it possessed at the time of manufacture. This process being early development phases.

Instability in modern formulation is often undetectable only after considerable storage period under normal conditions. To assess the stability of a formulated product it is usual to expose it to high stress conditions to enhance deterioration and therefore the time required for testing is reduced. Common high stresses are temperature and humidity. This will eliminate unsatisfactory formulation.

Strategy of stability testing:

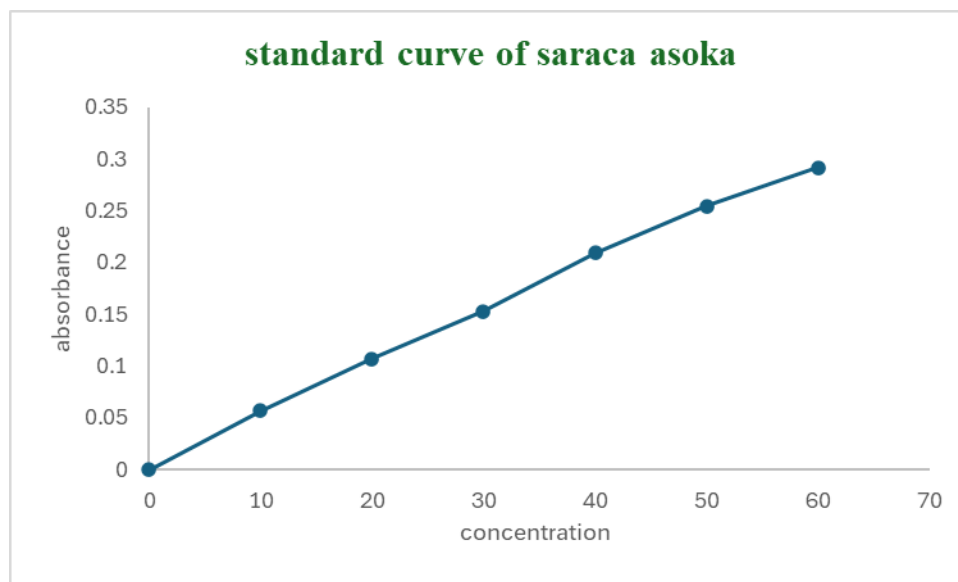
- The study of drug decomposition kinetics
- The development of stable dosage form
- Establishment of expiry date for commercially available drug product is some of the needs of stability testing
- Data from which study should be provided on at least 3 primary batches of the drug product

- The batches should be manufactured to a minimum of pilot scale
- Important point of view of the safety of the patient, patient receives a uniform dose of drug throughout the shelf life of the product⁹

Stability condition chart

Intended storage condition	Stability test method	ICH test temperature and humidity (period in months)	WHO test temperature and humidity (period in months)
Room temperature	Intermediate	30±2°C/65±5%RH	30±2°C/65±5%RH
	accelerated	40±2°C/75±5%RH	40±2°C/75±5%RH
Refrigerated	accelerated	25±2°C/60±5%RH	25±2°C/60±5%RH Or 30±2°C/65±5%RH
Freezer	Long term	-20°C/ambient	-20°C±5°C

Standard curve of saraca asoka



Standard curve of saraca asoka

standard curve of saraca asoka

s.no	Concentration of drug(µg/ml)	Absorbance at 240nm
1	0	0
2	10	0.0568
3	20	0.1074
4	30	0.1531
5	40	0.2094
6	50	0.2546
7	60	0.2916

Physical appearance

Colour : Brown

Odour : characteristic

Taste : astringent, slightly bitter

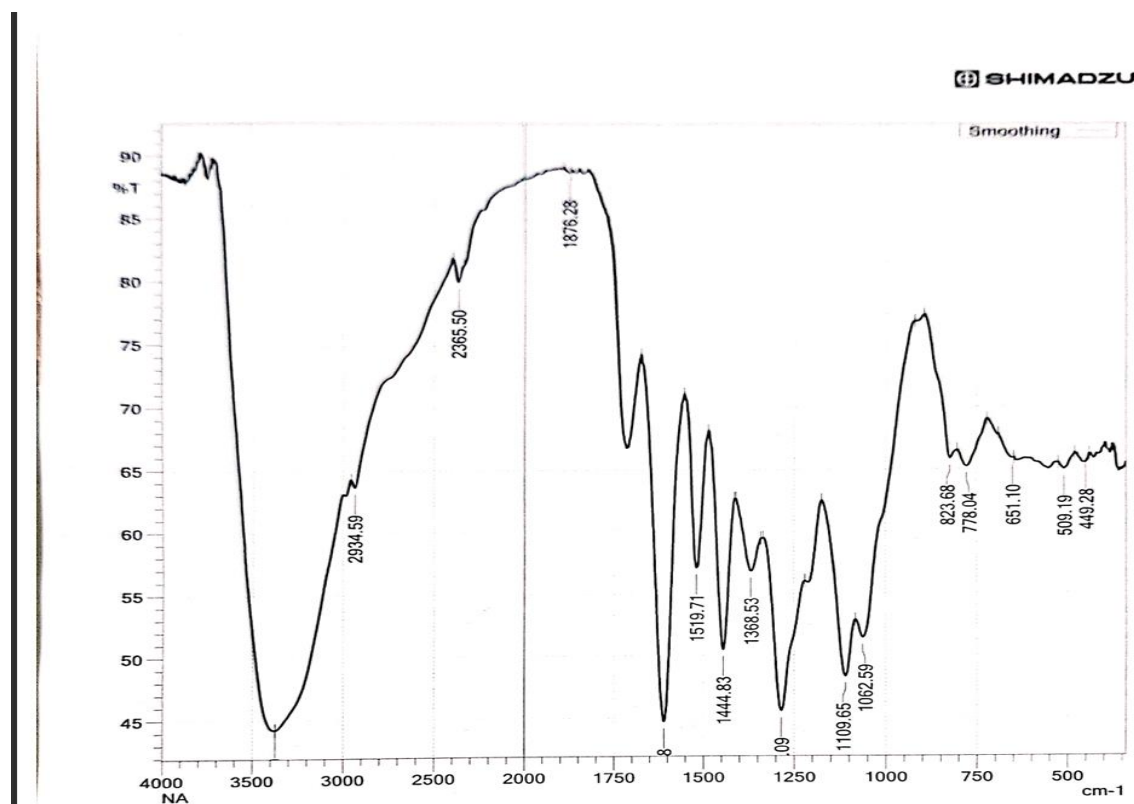
Solubility : solubility of drugs in various solvents is shown in the table

Solubility Profile of Saraca asoka**Solubility profile of saraca asoka**

solvent	Solubility
Distilled water	Soluble
Acidic acid	Partially soluble
chloroform	Partially soluble
Hot water	soluble

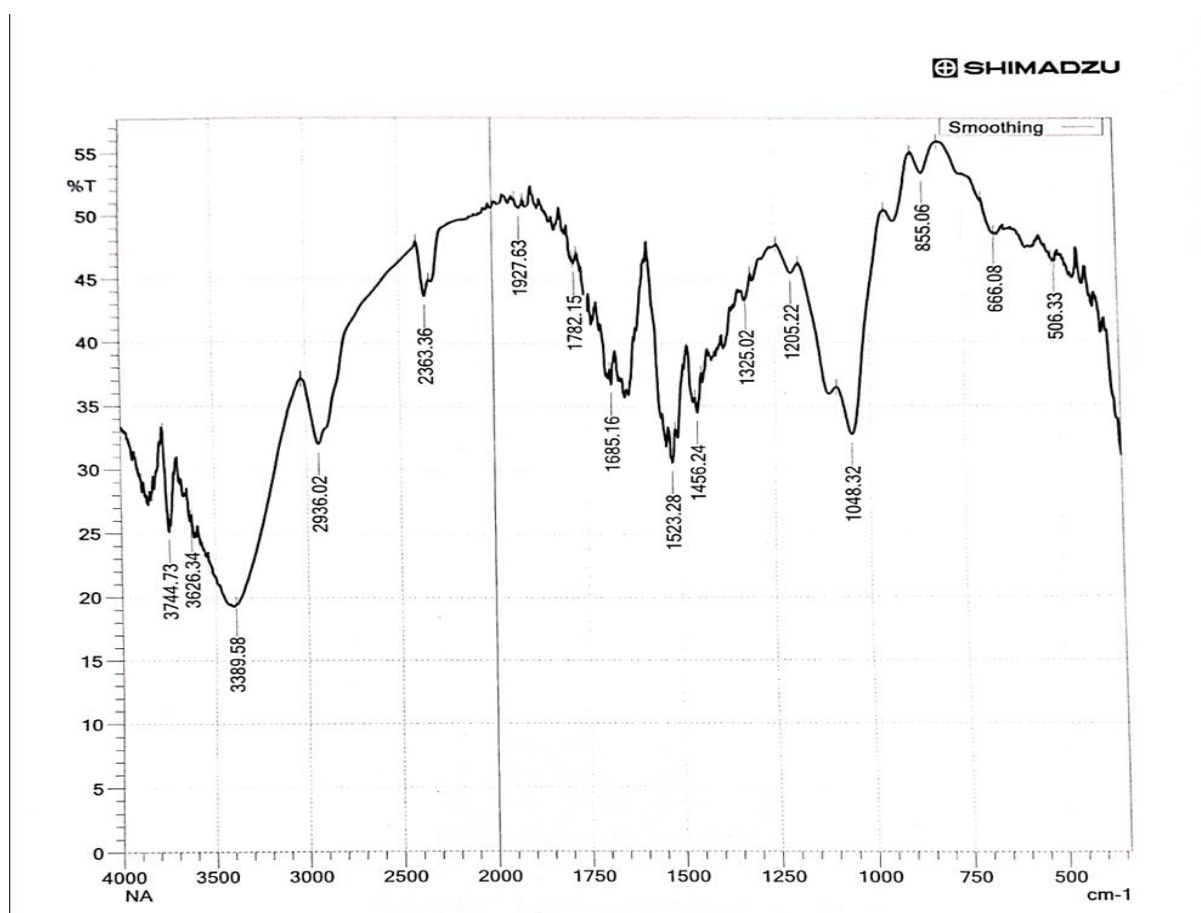
Discussion of solubility profile

The solubility profile of Saraca asoka extract was evaluated using different solvents such as distilled water, acidic medium, chloroform, and hot water. The results showed that the extract was completely soluble in distilled water and hot water, while it was only partially soluble in acidic solution and chloroform. The higher solubility observed in distilled water indicates that the major phytoconstituents of Saraca asoka possess polar characteristics, which dissolve easily in aqueous media. Similarly, hot water enhanced the solubility due to increased temperature, which improves the dissolution of active constituents. In contrast, the extract exhibited only partial solubility in chloroform, suggesting the presence of fewer non-polar compounds. The partial solubility in acidic medium indicates limited compatibility of the extract components under acidic conditions. Overall, the results suggest that distilled water is a more suitable solvent for dissolving Saraca asoka extract compared to acidic solution and chloroform, making it preferable for formulation development and further pharmaceutical applications.¹⁰

Compatibility study**FTIR studies****Interpretation of FTIR of *saraca asoka*****FTIR of *saraca asoka***

Wave number	Functional group
2934.59	C-H stretching
2365.50	Asymmetric stretching
1876.28	C=O stretching
1519.71	C=C stretching
1444.83	C-H bending
1368.53	-CH ₃ symmetric bending
1109.65	C-O stretching
1062.59	C-O stretching
823.68	Aromatic C-H out of plane bending

778.04	Aromatic C-H out of plane bending
651.10	C-Cl stretching
509.19	C-Br stretching
449.28	C-I stretching

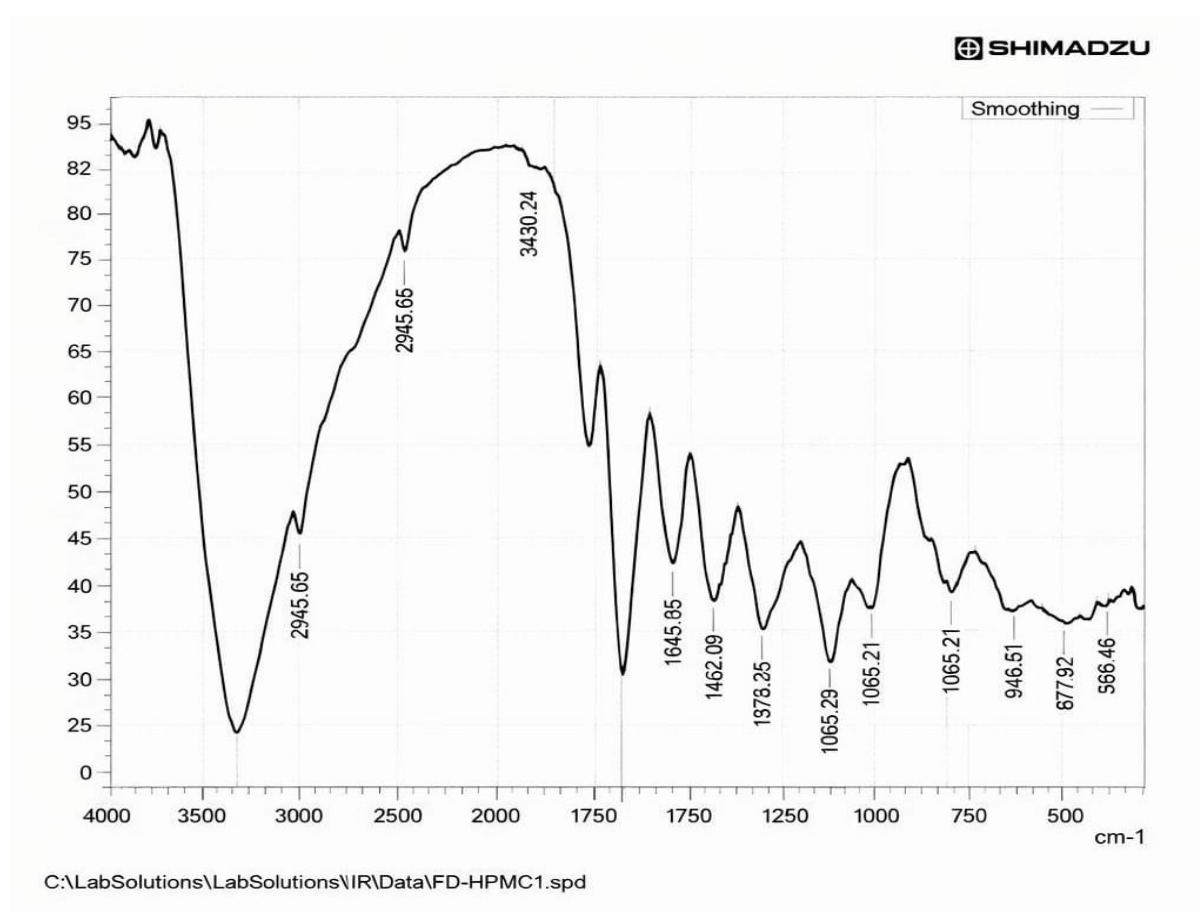


Interpretation of FTIR of patches

FTIR of patch

Wave number	Functional group
3744.73	Free O-H stretching
3626.34	O-H stretching
3388.58	O-H or N-H stretching

2936.02	C-H stretching
2363.36	C=O stretching
1927.63	C=O stretching
1782.12	C=O stretching
1685.16	C=O stretching
1523.28	N-O stretching
1456.24	C-H stretching
1325.02	C-N stretching
1205.22	C-O stretching
1048.32	C-O stretching
855.06	C-H out of plane bending
666.08	C-Cl stretching
506.33	C-Br stretching



Interpretation of FTIR of HPMC

FTIR of HPMC

Wave number	Functional group
3430.24	O-H stretching
2945.65	C-H stretching
1645.85	O-H bending
1462.09	CH ₂ bending
1378.25	C-H bending
1065.29	C-O-C stretching
946.51	C-O stretching
877.92	C-H deformation
566.46	Skeletal vibration

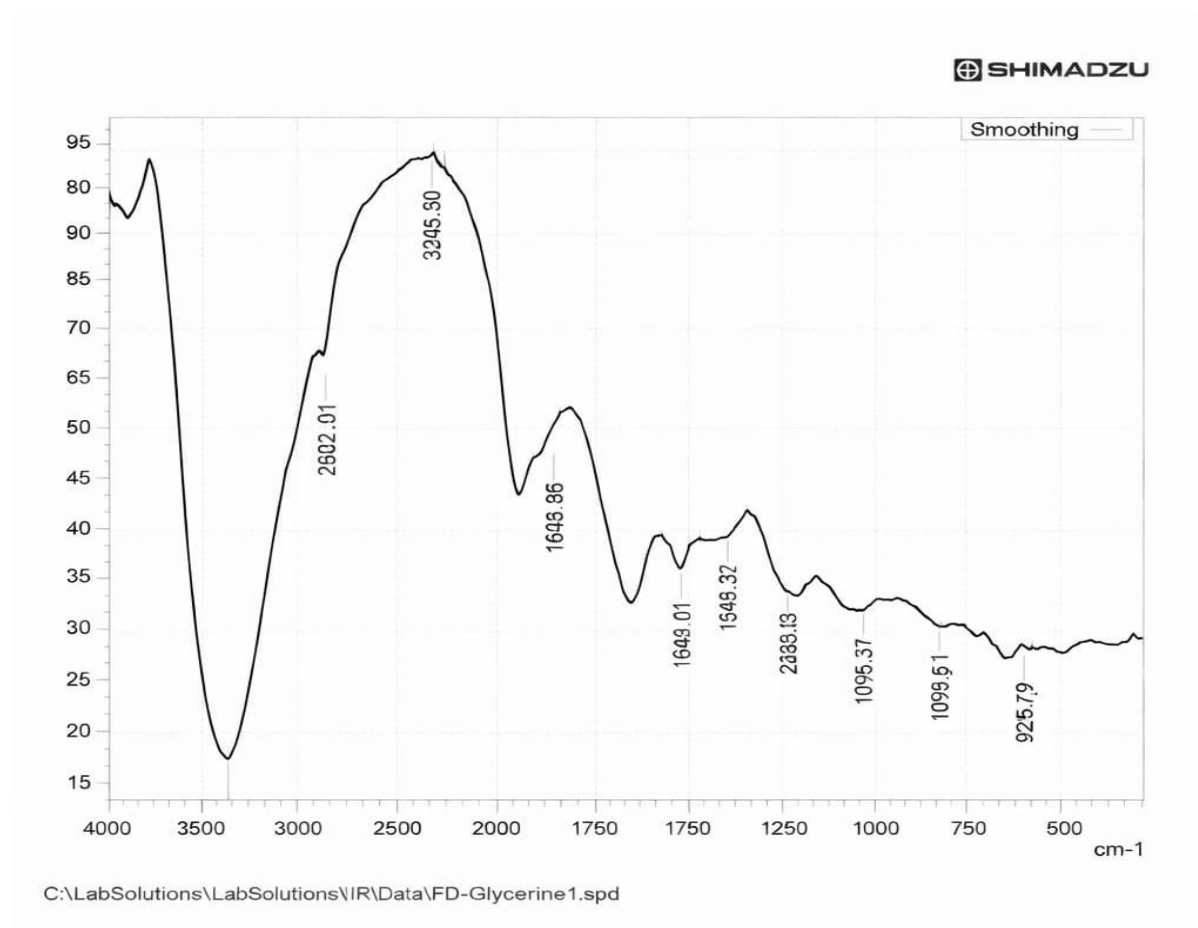
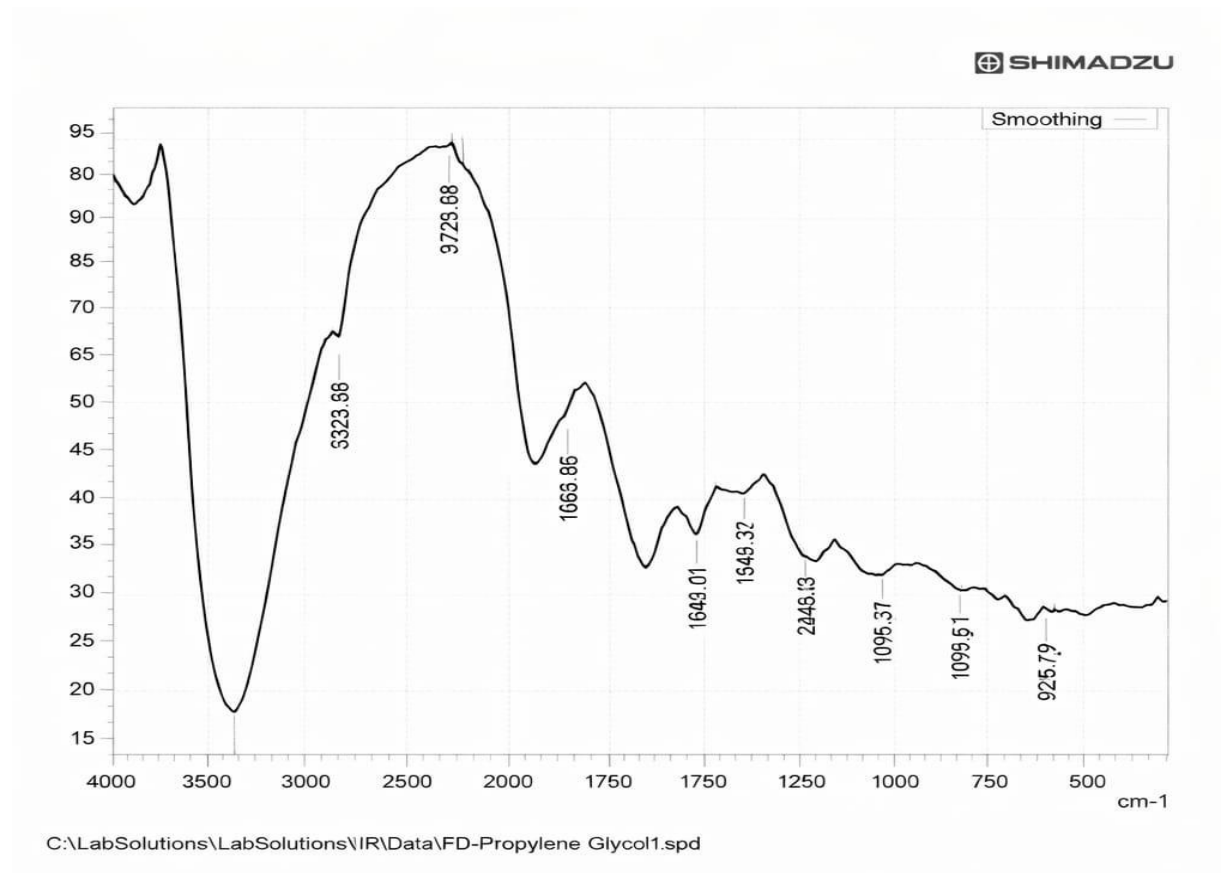
**Figure No:7.5 Interpretation of FTIR of glycerine**

Table no:7.6 FTIR of glycerine

Wave number	Functional group
3495.30	O-H stretching
2862.01	C-H stretching
1649.86	O-H bending
1549.32	C-H bending
1095.37	C-O stretching
925.79	C-O stretching
1095.37	C-O stretching

**Interpretation of FTIR of propylene glycol****FTIR of propylene glycol**

Wave number	Functional group
3323.58	O-H stretching
2972.88	C-H stretching
1666.86	O-H bending
1649.01	O-H bending
1549.32	C-H bending
1099.51	C-O stretching
1095.37	C-O stretching
925.79	C-O stretching

Discussion of FTIR

The FTIR spectrum of the pure *Saraca asoka* extract was analyzed to identify the functional groups present in the phytoconstituents. The spectrum showed a broad peak around 3200–3500 cm^{-1} , which corresponds to the O–H stretching vibration of phenolic compounds and flavonoids present in the plant extract. A peak around 2920 cm^{-1} indicates C–H stretching of aliphatic groups. The absorption band observed near 1650–1700 cm^{-1} represents C=O stretching vibrations, suggesting the presence of carbonyl groups. Peaks in the range of 1400–1500 cm^{-1} correspond to aromatic C=C stretching, indicating aromatic ring structures. Additionally, peaks around 1000–1300 cm^{-1} indicate C–O stretching vibrations, confirming the presence of alcohols, ethers, and glycosidic compounds. These peaks confirm the presence of important phytoconstituents such as flavonoids, tannins, and glycosides in *Saraca asoka*.

The FTIR spectrum of HPMC (Hydroxypropyl Methylcellulose) was recorded to confirm its functional groups and compatibility with the drug. The spectrum exhibited a broad absorption peak around 3200–3400 cm^{-1} , which corresponds to O–H stretching vibrations typical of cellulose derivatives. Peaks observed near 2900 cm^{-1} represent C–H stretching vibrations of the polymer backbone. The strong absorption bands in the region of 1000–1200 cm^{-1} indicate C–O–C ether

linkages present in the cellulose structure. These peaks confirm the characteristic structure of HPMC and its suitability as a film-forming polymer in transdermal patch formulation.

The FTIR spectrum of Propylene Glycol was analyzed to identify its functional groups. The spectrum showed a broad peak around 3300–3400 cm^{-1} indicating O–H stretching vibrations due to the presence of hydroxyl groups. Peaks around 2870–2930 cm^{-1} correspond to C–H stretching vibrations of aliphatic carbon chains. The absorption band near 1050–1150 cm^{-1} indicates C–O stretching vibrations, which confirms the presence of alcohol functional groups. These peaks are consistent with the chemical structure of propylene glycol and indicate its role as a solvent and plasticizer in the formulation.

The FTIR spectrum of Glycerin (Glycerol) was analyzed to confirm its structural characteristics. A strong broad peak around 3200–3400 cm^{-1} corresponds to O–H stretching vibrations, which are typical for polyhydric alcohols. Peaks near 2850–2950 cm^{-1} represent C–H stretching vibrations of aliphatic groups. The peaks observed around 1000–1100 cm^{-1} correspond to C–O stretching vibrations, indicating the presence of alcohol functional groups. These results confirm the typical spectral pattern of glycerin and demonstrate its suitability as a humectant and plasticizer in the transdermal patch formulation.

The FTIR spectrum of the final formulated transdermal patch containing Saraca asoka extract and excipients was analyzed to evaluate possible drug–excipient interactions. The characteristic peaks corresponding to O–H stretching (around 3200–3400 cm^{-1}), C–H stretching (around 2900 cm^{-1}), C=O stretching (around 1650 cm^{-1}), and C–O stretching (around 1000–1200 cm^{-1}) were clearly observed in the spectrum. These peaks correspond to both the drug and the excipients used in the formulation. No significant shift, disappearance, or appearance of new peaks was observed. This indicates that there is no chemical interaction between Saraca asoka extract and the excipients used in the formulation. Therefore, the FTIR study confirms the compatibility and stability of the drug within the polymer matrix of the transdermal patch.¹¹

Physiochemical Evaluation of Best three Formulations**Uniformity of Weight**

S.No	Formulation code	Weight(g)
1	P₁	0.21±0.72
2	P₂	0.36±0.1
3	P₃	0.40±0.42

Mean ±S. D: n=3**Thickness of the Patch**

S.NO	Formulation code	Thickness(mm)
1	P ₁	0.15±0.51
2	P ₂	0.23±0.45
3	P ₃	0.27±0.60

Mean ±S. D: n=3**Drug content determination**

S.NO	Formulation code	% Drug content
1	P ₁	95.44±0.03
2	P ₂	95.81±0.63
3	P ₃	95.69±0.66

Mean ±S. D: n=3**Folding Endurance**

S.NO	Formulation code	Folding Endurance(No'S)
1	P ₁	260±0.05
2	P ₂	268±0.55
3	P ₃	239±80

Mean ±S. D: n=3

Percentage Moisture Uptake

S.NO	Formulation code	% Moisture Uptake
1	P ₁	2.04±0.052
2	P ₂	2.13±0.07
3	P ₃	1.95±1.1

Mean ±S. D: n=3

Percentage Moisture Content

S.NO	Formulation code	% Moisture Content
1	P ₁	0.565±0.59
2	P ₂	1.921±0.3
3	P ₃	1.640±0.03

Mean ±S. D: n=3

Surface PH Determination

S.NO	Formulation code	Surface PH of patches
1	P ₁	6.1±0.03
2	P ₂	7.1±0.10

3	P ₃	6.0±0.70
---	----------------	----------

Mean ±S. D: n=3

Percent Elongation

S.NO	Formulation code	% Elongation (%mm)
1	P ₁	65±0.51
2	P ₂	83±0.41
3	P ₃	75±1.20

Mean ±S. D: n=3

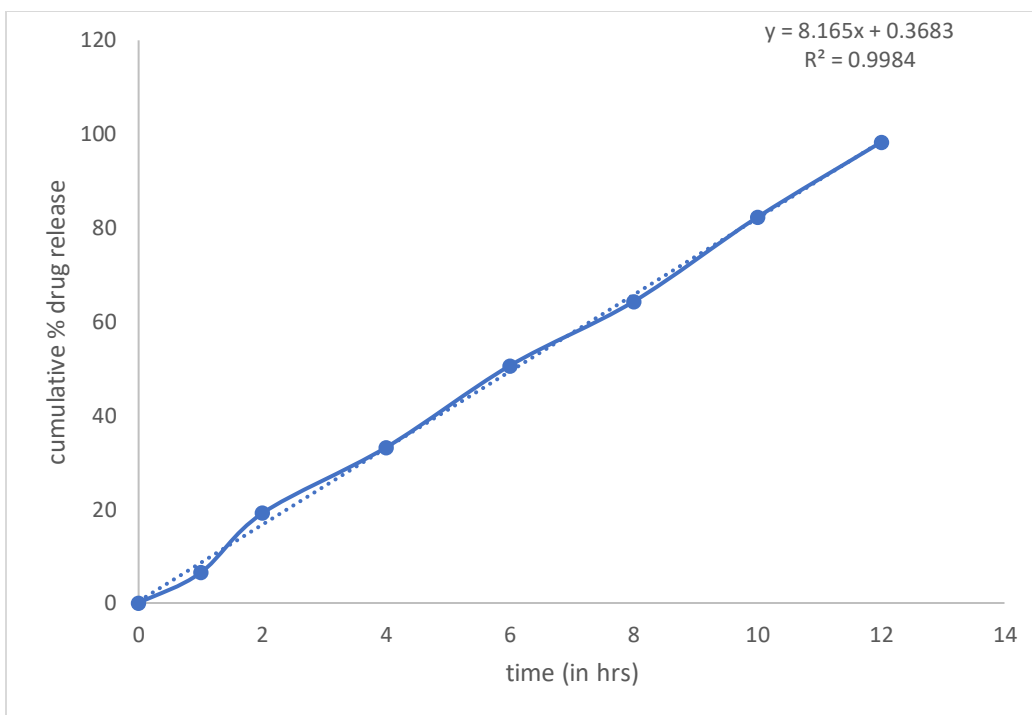
Tensile Strength

S.NO	Formulation code	Tensile strength (kg mm ²)
1	P ₁	3.380±0.04
2	P ₂	5.398±0.64
3	P ₃	6.460±64

Mean ±S. D: n=3

***In vitro* drug release profile kinetics of P1**

Time in minutes	% drug release
1	6.43±0.62
2	19.13±0.06
4	33.17±0.41
6	50.59±0.41
8	64.26±0.92
10	82.23±0.46
12	98.23±0.53

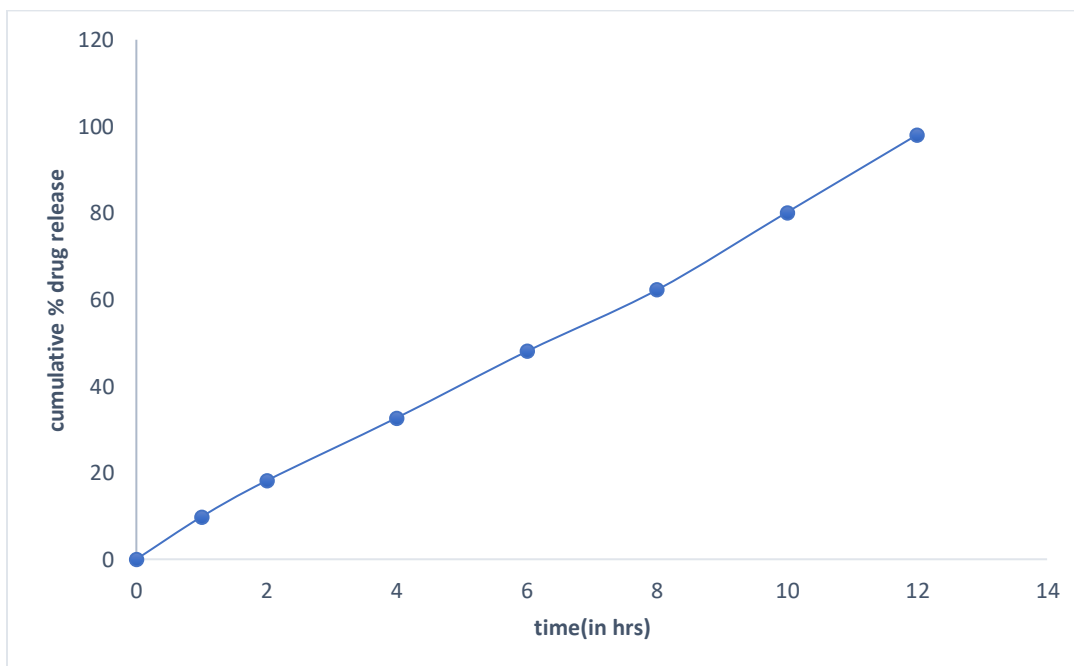


***In vitro* drug release profile of P1**

***In vitro* drug release profile of P2**

Time in min	% drug release
1	9.79±0.59
2	18.13±1.23
4	32.65±1.24
6	48±0.23
8	62.19±0.91
10	80.13±0.72

12	98.01±0.56
----	------------

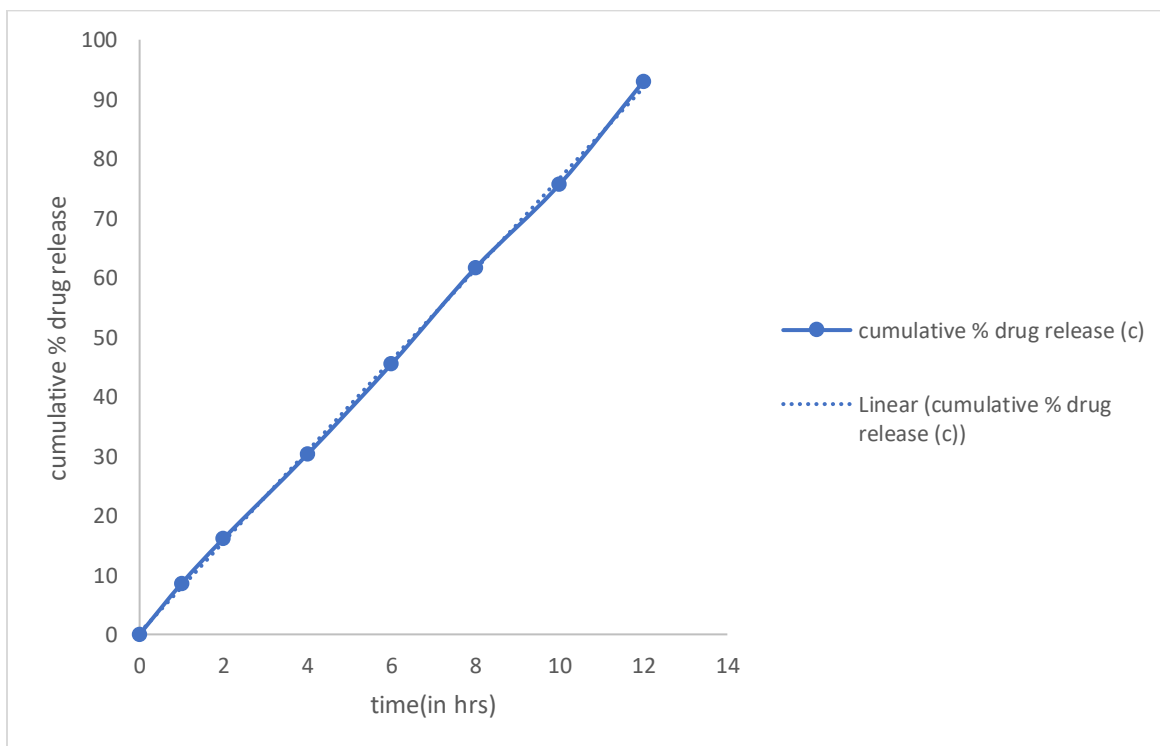


***In vitro* drug release profile of P2**

***In vitro* drug release profile of P3**

Time in minutes	%drug release
1	8.56±0.16
2	16.13±1.2
4	30.3±0.59
6	45.46±0.48

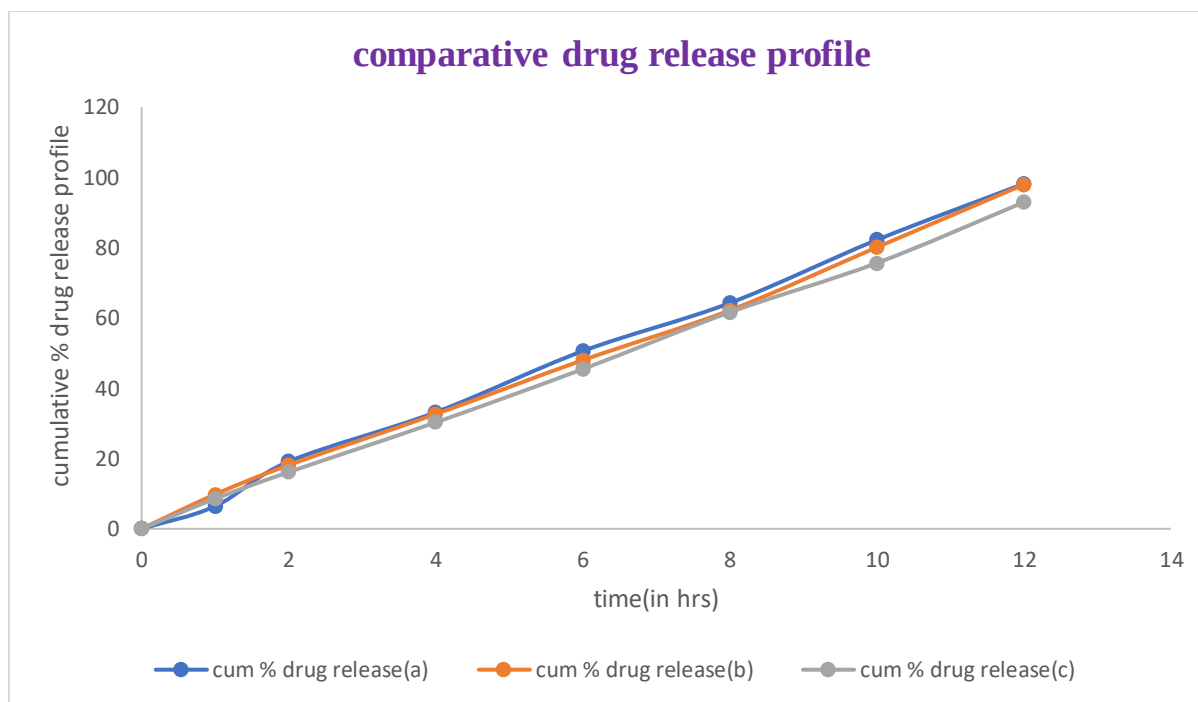
8	61.64±0.73
10	75.65±0.41
12	92.97±0.08



***In vitro* drug release profile of P3**

Comparative *in vitro* drug release profile

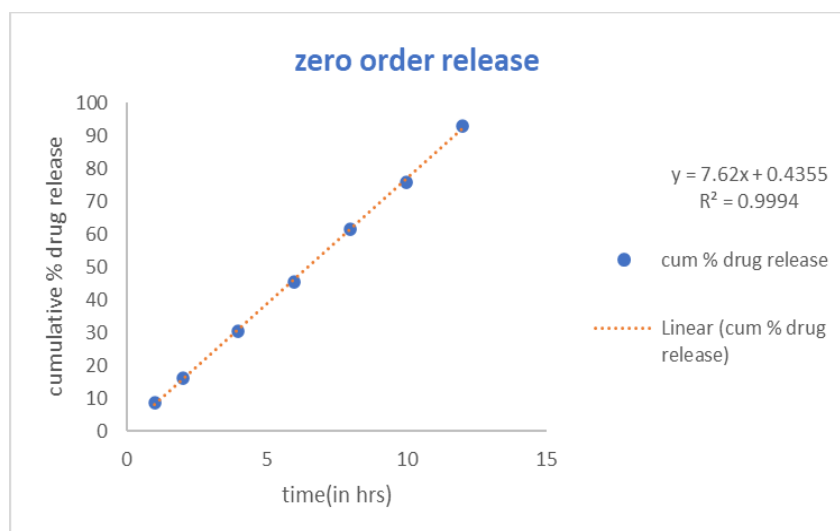
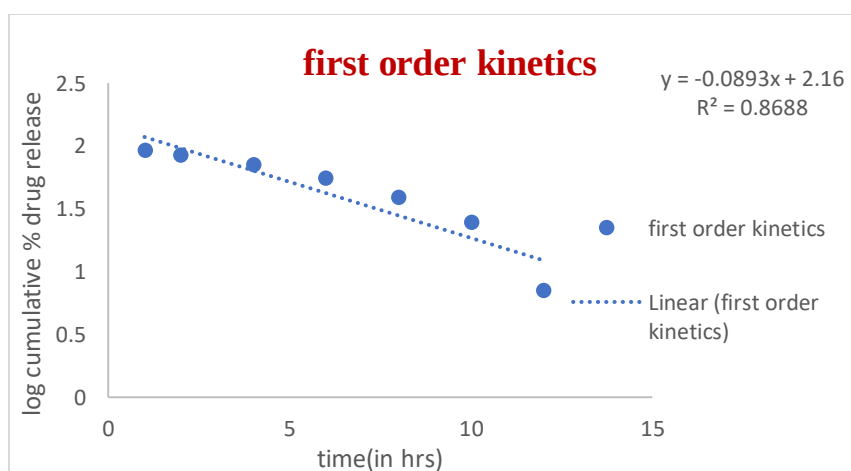
S. no	P1	P2	P3
0	0	0	0
1	6.43±0.62	9.79±0.59	8.56±0.16
2	19.13±0.06	18.13±1.23	16.13±1.2
4	33.17±0.41	32.65±1.24	30.3±0.59
6	50.59±0.41	48±0.23	45.46±0.48
8	64.26±0.92	62.19±0.91	61.64±0.73
10	82.23±0.46	80.13±0.72	75.65±0.41
12	98.23±0.53	98.01±0.56	92.97±0.08

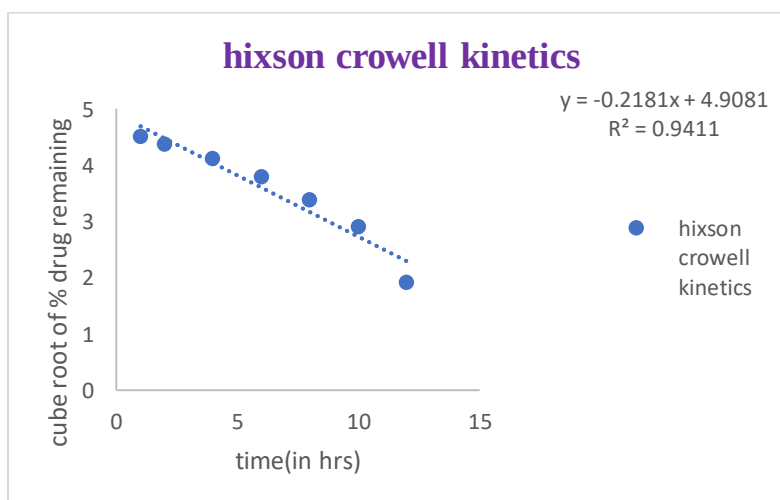
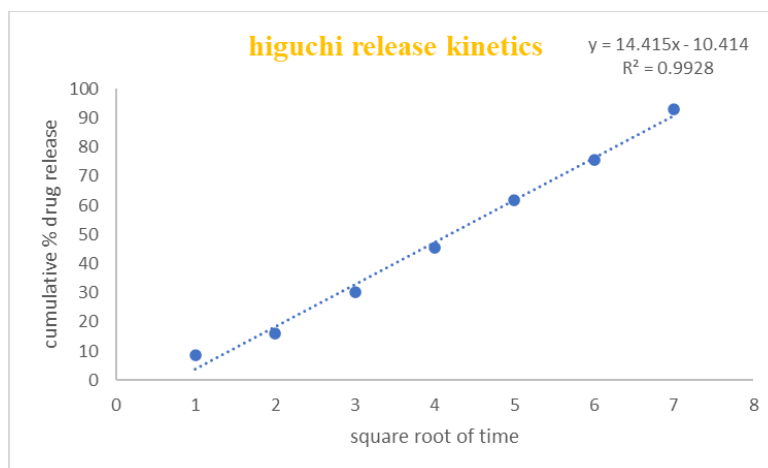
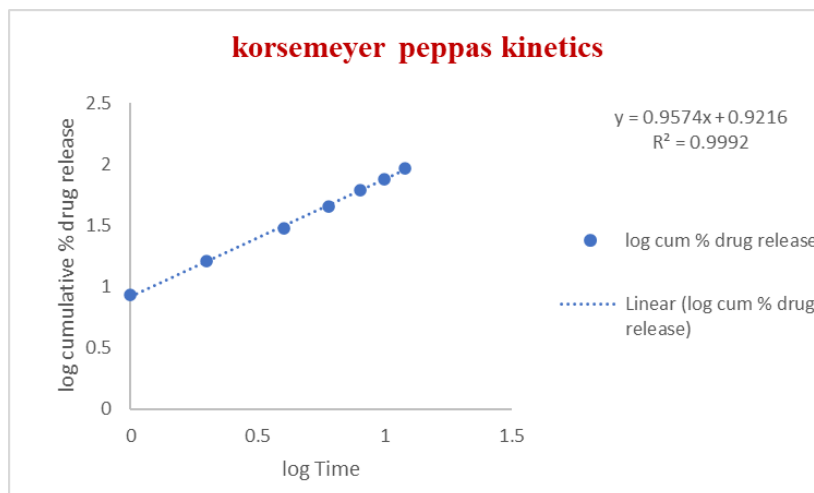


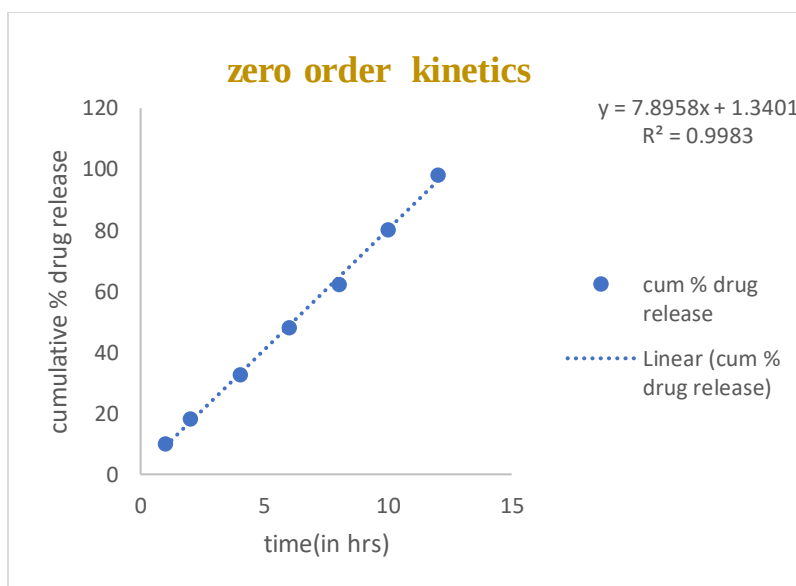
Comparative *in vitro* drug release profile



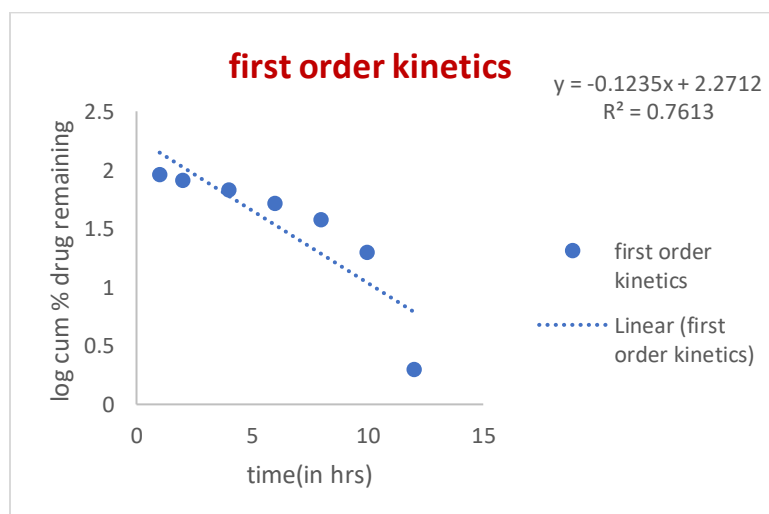
Diffusion study of P₃ patches

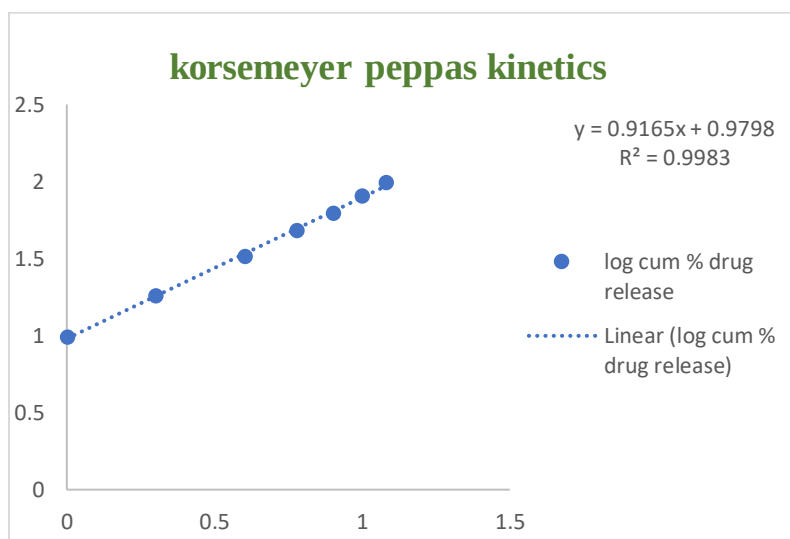
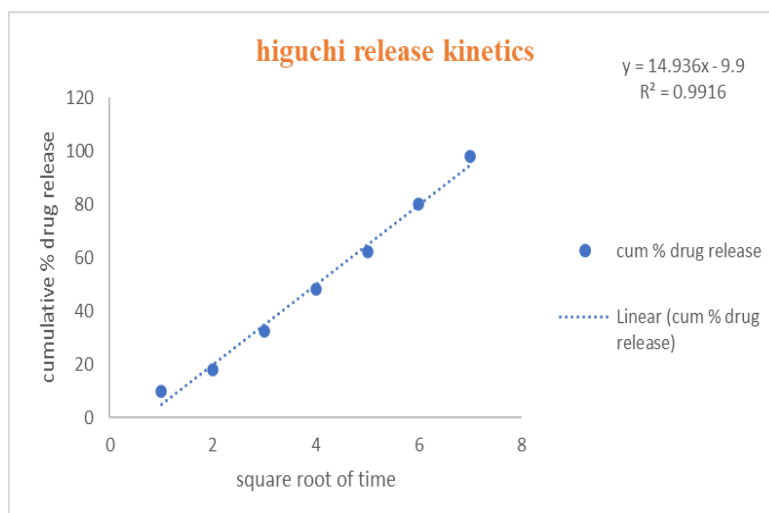
Release kinetics**Release kinetics of P1**

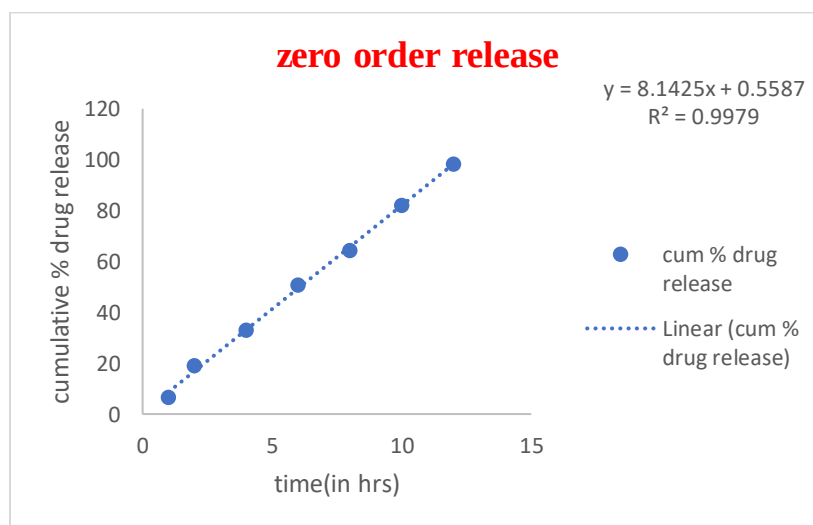
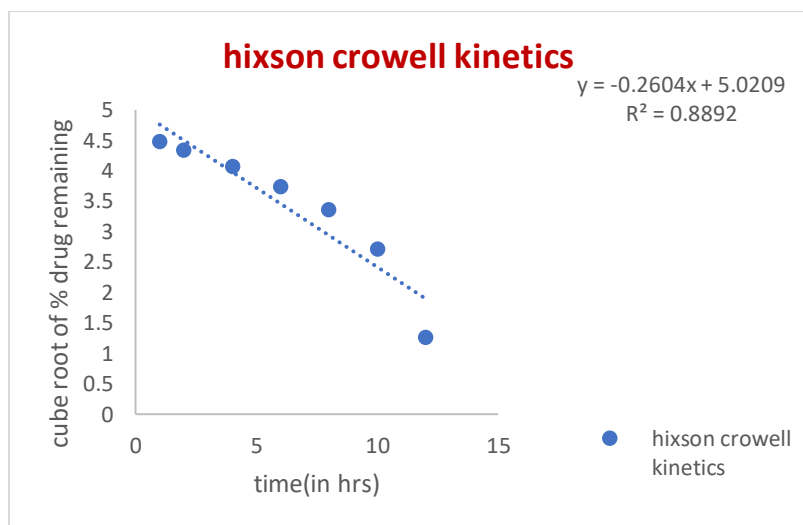




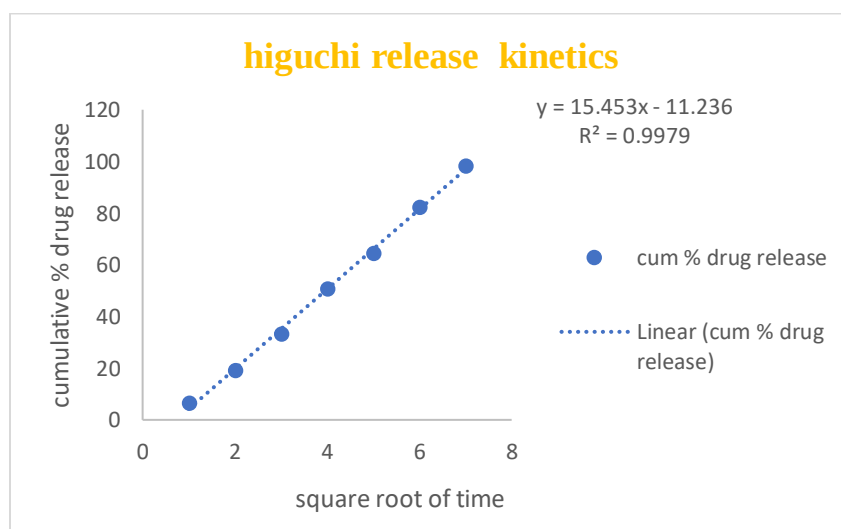
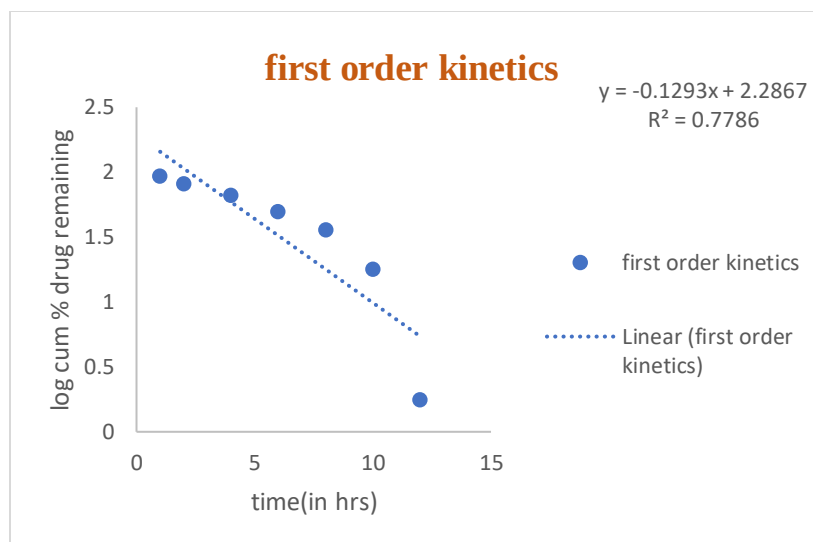
Release kinetics of P2

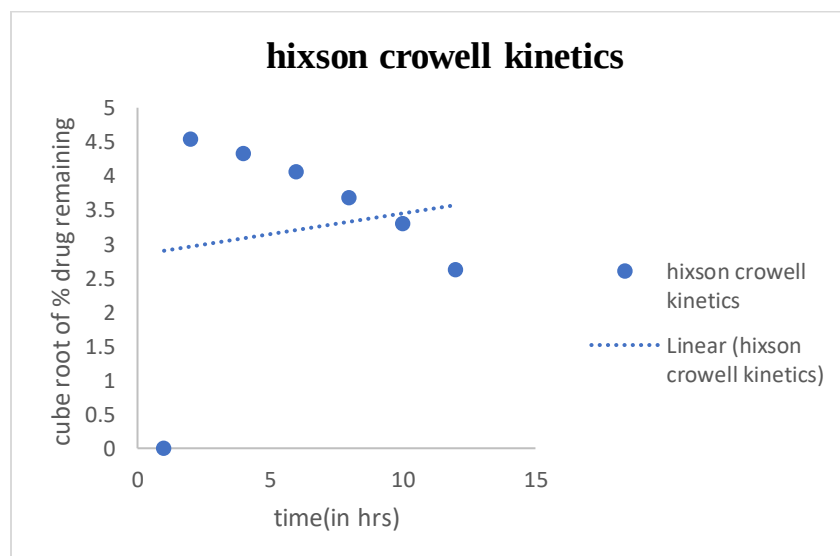
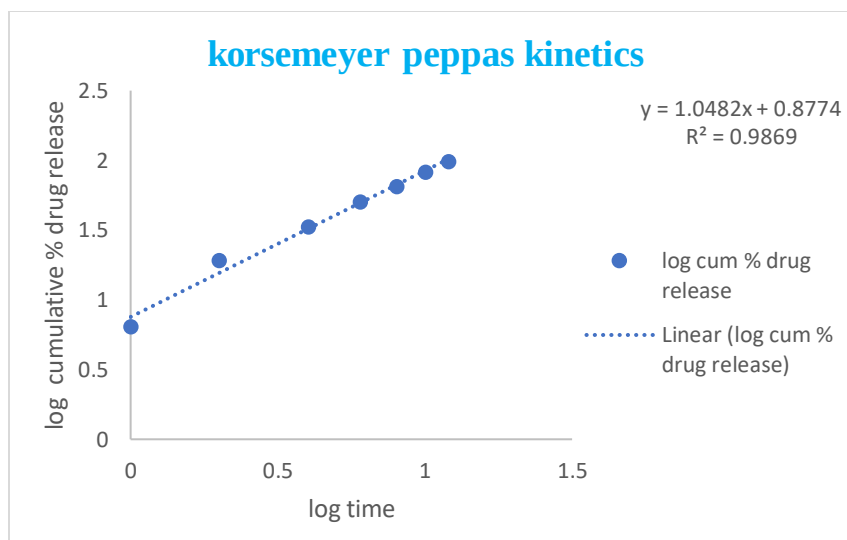






Release kinetics of P3





Observation:

The release data were analysed as per the zero order, first order, Higuchi korsmeyer peppas and Hixon crowell model to know the release pattern and mechanism of drug release from the saraca asoka transdermal patches Based on the findings it was determined that korsmeyer peppas model had the highest correlation coefficient, $R^2=0.9992$ and was therefore the model that best fit the optimised transdermal patches.

Stability study of saraca asoka transdermal patches

parameter	Room temperature	40±2°c & RH 70± 5%
Visual appearance	Transparent	Transparent
Initial	No change	No change
At the end of 1 st month	No change	No change
At the end of 2 nd month	No change	No change
At the end of 3 rd month	No change	No change
colour	Dull white	Dull white
Initial	No change	No change
At the end of 1 st month	No change	No change
At the end of 2 nd month	No change	No change
At the end of 3 rd month	No change	No change
Texture	Smooth	Smooth
Initial	No change	No change
At the end of 1 st month	No change	No change
At the end of 2 nd month	No change	No change
At the end of 3 rd month	No change	No change
Drug content	No change	No change
Initial	96.24%	96.24%
At the end of 1 st month	96.22%	96.14%
At the end of 2 nd month	95.95%	95.01%
At the end of 3 rd month	95.21%	94.06%

conclusion

The present research work was successfully carried out with the objective of developing a novel herbal transdermal patch of *Saraca Asoka* for the effective management of dysmenorrhea, a condition that significantly affects the physical, psychological, and social well-being of women of reproductive age. Dysmenorrhea remains a major health concern worldwide, and although several

conventional therapeutic options are available, their long-term usage is often limited by undesirable side effects, reduced patient compliance, and systemic complications. In this context, the integration of traditional herbal medicine with advanced drug delivery systems represents a promising approach to improve therapeutic outcomes while minimizing adverse effects.

The outcomes of this study highlight the potential of herbal transdermal patches as an effective alternative therapeutic strategy for dysmenorrhea management. The developed formulation not only addresses the limitations associated with conventional oral dosage forms but also offers a non-invasive, painless, and patient-friendly mode of drug administration. This approach is particularly advantageous for women who experience gastrointestinal discomfort or intolerance with oral medications or those seeking non-hormonal treatment options for menstrual pain relief.

The formulated herbal transdermal patches were subjected to comprehensive physicochemical evaluation to ensure their suitability for transdermal application. Parameters such as thickness uniformity, weight variation, folding endurance, tensile strength, moisture content, moisture uptake, surface pH, and drug content uniformity were found to be within acceptable limits. These results indicate that the patches possess adequate mechanical strength, flexibility, and stability required for effective skin application and patient handling. The surface pH of the patches was found to be compatible with the physiological pH of the skin, suggesting minimal risk of skin irritation or sensitization upon prolonged use.

Drug content uniformity studies confirmed that the herbal constituents were evenly distributed throughout the transdermal patches, ensuring consistent drug delivery and therapeutic efficacy.

In conclusion, the novel herbal transdermal patch of *Saraca Asoka* developed in this study can be considered a promising and innovative delivery system for the effective management of dysmenorrhea. The formulation successfully combines the benefits of traditional herbal medicine with the advancements of transdermal drug delivery technology. Although the results obtained from in-vitro evaluations are encouraging, further in-vivo studies and clinical trials are recommended to establish the safety, efficacy, and pharmacokinetic profile of the formulation in human subjects. With appropriate optimization, standardization, and large-scale validation, this herbal transdermal patch has the potential to be developed into a commercially viable and clinically

effective product for menstrual pain management, thereby contributing to improved women's healthcare and quality of life.

Reference

1. Dawood MY. Primary dysmenorrhea: Advances in pathogenesis and management. *Obstet Gynecol.* 2006;108:428–441.
2. Harel Z. Dysmenorrhea in adolescents and young adults. *Ann N Y Acad Sci.* 2008;1135:185–195.
3. Osayande AS, Mehulic S. Diagnosis and initial management of dysmenorrhea. *Am Fam Physician.* 2014;89:341–346.
4. Iacovides S, Avidon I, Baker FC. What we know about primary dysmenorrhea. *Hum Reprod Update.* 2015;21:762–778.
5. Guy RH, Hadgraft J. *Transdermal Drug Delivery.* New York: Marcel Dekker; 2003. p. 1-20.
6. Rathbone MJ. *Modified Release Drug Delivery Technology.* New York: Informa Healthcare; 2008. p. 55–70.
7. Hadgraft J, Lane ME. Skin permeation: The years of enlightenment. *Int J Pharm.* 2005;305:2–12.
8. Shaikh N, Srivastava R. A review on transdermal drug delivery through patches. *IP Indian J Clin Exp Dermatol* 2024;10(2):113-121
9. Khare CP. *Indian Medicinal Plants: An Illustrated Dictionary.* New York: Springer; 2007. p. 602–604.
10. Mukherjee PK. *Quality Control of Herbal Drugs.* New Delhi: Business Horizons; 2019. p. 268–270.
11. Evans WC. *Trease and Evans Pharmacognosy.* 15th ed. London: WB Saunders; 2002. p. 490–493.
12. Jain NK. *Controlled and Novel Drug Delivery.* 1st ed. New Delhi: CBS Publishers; 2008. p. 100–112.
13. Chien YW. *Novel Drug Delivery Systems.* 2nd ed. New York: Marcel Dekker; 1992. p. 301–330.
14. Barry BW. *Dermatological formulations: Percutaneous absorption.* New York: Marcel Dekker; 1983. p. 25–35.

15. Berek JS. Berek & Novak's Gynecology. 15th ed. Philadelphia: Lippincott Williams & Wilkins; 2012. p. 470–475.
16. Speroff L, Fritz MA. Clinical Gynecologic Endocrinology and Infertility. 8th ed. Philadelphia: Lippincott; 2011. p. 401–405.
17. Edmonds DK. Dewhurst's Textbook of Obstetrics and Gynaecology. 8th ed. Oxford: Wiley Blackwell; 2012. p. 54–57.
18. Fritz MA, Speroff L. Clinical Gynecologic Endocrinology. 9th ed. Philadelphia: Lippincott; 2015. p. 378–382.
19. Rowe RC, Sheskey PJ, Quinn ME. Handbook of Pharmaceutical Excipients. 7th ed. London: Pharmaceutical Press; 2012. p. 326–329.
20. Allen LV. Pharmaceutical Excipients: Properties and Applications. 3rd ed. London: Pharmaceutical Press; 2017. p. 210–215.
21. Ms. Shreya D. Shinde Review on Preformulation Studies of the Herbal Drugs International Journal of Enhanced Research in Medicines & Dental Care ISSN: 2349 – 1590, Vol. 11 Issue 5, May 2024.
22. Khandelwal KR practical pharmacognosy. 11th ed. Pune: Nirali Prakashan 2004.p.149-56.
23. Instrumental Methods of Analysis by Hobart H. Willard et al. McGraw-Hill; 7th Edition.
24. P. Pradhan *et al* Saraca Asoka on Review Journal of Chemical and Pharmaceutical Research, 2009, 1 (1): 62-71.
25. Sakshi D. Ghodke Formulation and Evaluation of Transdermal Patch for Pain Management. International Journal of Creative Research Thoughts ISSN: 2320-2882, Volume 13, Issue 5 May 2025.
26. Joshi, D.D. (2012). FTIR Spectroscopy: Herbal Drugs and Fingerprints. In: Herbal Drugs Fingerprints Springer, india. [https:// doi.org/10.1007/978-81-322-0804-4_7](https://doi.org/10.1007/978-81-322-0804-4_7).
27. Jayita Saha, Taniya Mitra, Kamala Gupta, Sumona Mukherjee, International Journal of Pharmacy and Pharmaceutical Sciences, 4(1), 96 (2012).
28. Formulation and Evaluation of Transdermal Patches of Boerhaviadiiffusa Linn. International Journal of Pharmaceutical Science Invention ISSN (Online): 2319-6718, Volume 12 Issue 6 | Nov. -Dec., 2023 | PP. 04-09
29. Sulaiman C. T., identification of validated substitute for asoka by phytochemical and pharmacological evaluations C. T.*et al.* future journal of pharmaceutical sciences.

30. E. Aswini. Formulation and evaluation of herbal transdermal patches for rheumatoid arthritis.
International journal of multidisciplinary research E-ISSN: 2582-2160.