Research Article *Open Access*

Journal of Advanced Diabetes Research

DOI: *doi.org/10.63721/26JADR0109*

Formulation and In-Vitro Evaluation of Fenugreek Extract Loaded Herbal Transdermal Patch for Controlled Delivery in Diabetes Mellitus

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Citation: *Jeyatheepan Jeyaretnam (2026) Obesity-Driven Chronic Disease: A Systematic Review of Modern Therapeutic Perspectives. J of Advanced Diabetes Research 2(2), 01-08. WMJ/JADR-109*

Abstract

The investigation of fenugreek seed extract transdermal patches for the treatment of diabetes mellitus is reported in this paper. Trigonella foenumgraecum, a member of the Leguminosae family, is the source of fenugreek seed extract. used to decrease blood cholesterol, treat diabetic mellitus, and other conditions. It contains active ingredients such as trigonelline, choline, and others that contribute to the antidiabetic effects. The extract's galactomannans content is what hydrates the skin. As a result, a topical fenugreek extract formulation may improve penetration and be primarily absorbed at a particular skin absorption site. Fenugreek extract-containing transdermal patches were created and assessed according to a number of criteria. After six hours, the drug content shows over 90% drug release. The 2:2 ratio was determined to have the maximum release among the various formulations. The findings show that a transdermal drug delivery system's regulated release can also increase therapeutic efficacy, patient compliance, and prevent adverse effects that come with traditional medications.

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Submitted: 24.03.2026 **Accepted**: 28.03.2026 **Published**: 05.05.2026

Keywords: Diabetes Mellitus, Trigonelline, Fenugreek Seed Extract, Transdermal Patch

Introduction

Transdermal drug delivery systems (TDDS) are devices, or adhesives, used to deliver drugs to the skin via the route of the skin at pre-programmed rates and with a defined surface area. The drugs are delivered to the skin at the appropriate rate to maintain the plasma level of drug on an ongoing basis [1].

In addition to being able to deliver drugs for the treatment of systemic disease, transdermal drug delivery has generated considerable interest over the past few years because of the transdermal route of delivery's ability to provide high bioavailability

of drugs due to the inability of many drugs to pass through the skin, after first-pass metabolism. In other words, the advantage of transdermal drug delivery has the added benefit of being able to deliver drugs for extended periods of time [2].

Transdermal delivery has other advantages such as providing for self-administration of drug and allowing for rapid termination of the drug when required, thus leading to improved patient compliance. Despite the advantages associated with transdermal drug delivery, only a limited number of drugs are suitable for this method of drug delivery due to the low permeability of most drugs across the skin. The stratum corneum has long been recognized as an effective barrier to penetration of drug through the skin. Several methods have been proposed to help overcome the limitations of transdermal drug delivery which include—use of penetration enhancers, such as DMSO (Dimethyl sulfoxide), Pyrollidone, Urea and the development of electro transport-aided transdermal drug delivery continue to evolve with attempts to develop effective transdermal delivery systems for a variety of drugs [3].

Transdermal permeation is characterized by the ability of a topically applied drug to penetrate the stratum corneum (the skin's barrier). There are three ways a drug can penetrate through the skin: through the intact stratum corneum, through hair follicles, and through sweat glands [4].

Initially, through the transient diffusion process, the dry molecules will penetrate through hair follicles and/or sweat glands and then through the follicular epithelium and/or sebaceous glands. However, once a steady state of absorption has been attained, diffusion through the stratum corneum will be the primary means of transdermal drug transport. Herbal therapy provides a rational approach to treating many (internal) diseases deemed untreatable or difficult to treat by other medical disciplines and provides a strong focus on maintaining the individual's positive health.

Herbal therapy's primary objective is to prevent and cure disease. Herbal patches are a type of medicated patch that provide a growing number of herbal products as the use of herbal products increases in popularity due to decreased side effects and increased patient compliance [5].

India could be an emerging leader in the global herbal product market due to the increasing use of herbs worldwide. Diabetes Mellitus is the most popular Endocrine disorder, marked by hyperglycemia, glucosuria, hyperlipemia, and a negative nitrogen balance. Diabetes Mellitus (DM) causes elevated blood glucose levels; while also causing disruption of carbohydrate, fat & protein metabolism.

A variety of synthetic & herbaceous natural agents are used to treat diabetes mellitus type 2 (component of non-insulin dependent diabetes mellitus) as treatment for hyperglycemia.

Trigonella foenum-graecum (fenugreek), is one of several herbaceous natural agents that have been investigated for potential antidiabetic effects. Fenugreek is an annual herbaceous plant belonging to the leguminous family, that has been used as both food & medicine, and contains numerous essential nutrients (e.g. Fe, P, or S) and many active ingredients that produce antiphospholipid activities. Several of the active ingredients that result in fenugreek's antidiabetic properties include- pyridine type alkaloids (gentianine, trigonelline, choline) flavonoids/orientin, vitexin; and steroidal saponins (diosgenin, yamogenin, gitogenin). Fenugreek is utilized to treat patients who develop NIDDM and has been shown effective in treating other conditions such as poor digestion (e.g. during convalescence), insufficient lactation, painful menstruation, nausea or vomiting during pregnancy. In patients with type 2 DM, the consumption of fenugreek seed has been shown to decrease glucose levels in patients; and may provide similar benefits in type 1 DM.

According to studies, it has been shown that fenugreek seed extract increases blood plasma insulin levels in an animal model. It has also been reported that one of the main free amino acids present in fenugreek seeds, 4-hydroxy isoleucine, induces the secretion of insulin from a perfused pancreas in vitro [7].

Over the past years, researchers have also demonstrated that topical application of fenugreek seed extract results in skin hydration due to the galactomannan content of the extract. Once hydrated, the stratum corneum of the epidermis possesses permeability

toward many herbs, including pharmaceuticals [8].

As a result, the use of a topical formulation containing fenugreek seed extract may enhance the permeability and absorption of active constituents responsible for producing antidiabetic activity, including pyridine-type alkaloids, including gentianine, trigonelline, and choline, and flavonoids such as orientin, vitexin, and quercetin; steroidal saponins including diosgenin, yamogenin, and gitogenin through the skin and into systemic circulation. Additionally, transdermal patches could enhance the permeation and absorption of these same constituents through the skin if used as a transdermal patch containing fenugreek extract. Therefore, the objective of this study was to develop a transdermal patch of fenugreek seed extract for sustained or controlled release of medications for the treatment of excessive diabetes mellitus [9].

Materials and Methods

Reagents and materials used for this study included Hydroxy Propyl Methyl Cellulose (HPMC) E15-LV, HPMC 15CPS, HPMC 50CPS, and Disodium Methane Sulfoxide (DMSO) purchased from Central Drug House (P) Ltd in New Delhi; Propylene Glycol and Ethanol were purchased from Merk India Pvt Ltd in Mumbai, India. All reagents/chemicals were purchased at analytical grade.

Formulation of Transdermal Films of Fenugreek Seed Extract

The transdermal films of fenugreek seed extract were prepared by Petri plate technique [10,11].

Preparation of Casting Solution

Preparation of casting solutions involved the dissolution of numerous measured weights of various polymers that were weighed out in a ratio of the hydro alcoholic solution (Ethanol:Water) for two hours using a mechanical stirrer at 500 rpm, as well as allowing to swell at room temperature for one day. The 2g extracted from the previous step was also mixed with the ethanol:water polymer solution for approximately three hours using a mechanical stirrer at 500rpm; additionally, propylene glycol, the plasticizer used to prepare these polymer solutions, was thoroughly mixed with the other components through use of a mechanical stirrer at 500 rpm for two hours to create one homogeneous solution and adjusting the final volume to 40 milliliter with distilled water; lastly, all entrapments of air bubbles were removed by application of vacuum.

Preparation of Transdermal films

Petri-plates (40 ml of the casting solution was poured into each plate) were dried using hot air oven at 60 0C for 24 hrs. The films were obtained through peeling and cut into squares 3 cm x 3 cm (9 cm2) with each of the separate films containing 6.058 mg of Trigonelline. These films were put in desiccator for additional drying and wrapped in aluminum foil and then to provide unidirectional flux of drug from the transdermal films a backing layer was prepared using ethyl cellulose and cyanoacrylate adhesive. Transdermal films will be prepared using different polymer ratios, different plasticizer concentrations and different permeation enhancers.

Evaluation of Transdermal films

Visual Inspection

To evaluate certain organoleptic characteristics, the produced films were visually inspected for color, transparency, and homogeneity.

Film Thickness

The thickness of the films was measured at five different places on a single patch of each formulation using a screw gauge and the mean values were calculated [12].

Weight Variation

Films 2 × 3 cm2 in size were weighed on an electronic balance. The measurements were carried out in triplicates [13].

Drug Content

One film from each formulation was cut in to small pieces was transferred into a 100 ml beaker containing about 50 ml of phosphate buffer using a mechanical stirrer at 500 rpm for 6 h and filtered and the volume was made to 100 ml with phosphate buffer (pH 7.2). Suitable dilutions were prepared with phosphate buffer (pH 7.2). The absorbance will be measured using UV spectrophotometer (V-630, JASCO, Japan) at λ max 263 nm.

Folding Endurance

This gives an indication of the brittleness of the film. The film was repeatedly folded in the same spot until it broke. The folding endurance was taken as a function

of the number of times the film is folded before breakage. The experiment was done in triplicates and the mean ±SD was calculated [14].

Tensile Strength

The tensile strength was determined using a Tensile strength apparatus. A pressure gauge could be selected based on the sample being tested using the gauge sector switch. Films that were 3cm in diameter (and free of air bubbles or other physical problems) were placed on the diaphragm plate, which was rotated until the wheel on top of the diaphragm plate was tight enough to fit the sample that it no longer rotated. The "Push" button was pushed until the sample broke. The pressure gauge provides a direct measure in Kg/cm2. Each film was measured 3 times. Tensile strength refers to the greatest amount of stress that can be applied at any point before the sample (the film) breaks.

Moisture absorption

Films of each formulation were accurately weighed and exposed to ambient atmospheric conditions of temperature (avg. temp 34 ^{0}C) and humidity (75 %) for three days. After three days, the films were again weighed and percentage moisture absorption was calculated.

In vitro drug release studies

A beaker containing a phosphate buffered solution (pH 7.2) maintained at 37 ± 0.5ºC and stirred at 100 RPM had 3 X 23 cm films of known dry weight and dimensions (when placed in the beaker) and were removed at 5-second intervals for 5 mL aliquots to be taken and replaced with 5 mL of fresh phosphate buffered solution. A UV/vis spectrophotometer (V-630: JASCO (Japan)) was used to determine the concentration of drug in each aliquot taken from the beaker using the standard curves determined with each film type in order to calculate a cumulative percentage of drug released as a function of time (sec) [15].

Results And Discussion

Visual Inspection

It was discovered that the transdermal films made with varying concentrations of polymers were smooth, flexible, opaque, sticky, and uniform. The presence of plasticizer could be the cause of this.

Film Thickness

The thickness of the film was observed to increase with the concentration of plasticizer and polymer. The film seems to have the perfect thickness for topical use.

Weight Variation

There was no discernible variation in the weight of the various formulations from the average value; all of the created formulations were consistent in weight. For the prepared films, the weight variation was determined to be between 0.89 ± 0.0115 and 0.96 ± 0.0152 gm.

Drug Content

It was determined that the drug content was within the limit, with percentages ranging from 80.00 to 90.00 in different formulations.

Folding Endurance

All nine films demonstrated good folding endurance, and it was found that the films' folding endurance rose as the polymer and plasticizer concentrations rose. As the films' folding durability rose, so did their flexibility.

Tensile Strength

Tensile strength provides information about the films' elasticity and strength. The relationship between polymer concentration and tensile strength revealed that the tensile strength rose in tandem with the polymer concentration. This could be because polymers are both supple and durable.

Moisture absorption

As the amounts of polymers increased, there was a shift in the moisture absorption of every formulation.

In vitro drug release study

The kind of polymer employed determines how the medication releases from the formulation. The maximum drug release from formulations F1–F3 was 89.62%, while the maximum drug release from other formulations was 94.1%. Formulations F1–F3 had a lower drug release than the others. Since trigonelline hydrochloride is a water-soluble compound found in fenugreek seed extract, the effect of other non-polar components in the extract was diminished as the concentration of hydrophilic polymer used in the patches increased and drug penetration through the patches increased. Drug release was enhanced by

formulations with higher polymer concentrations.

Conclusion

Transdermal patches of fenugreek seed extract were effectively created in this study, providing a viable and useful method for achieving the intended goal of diabetes mellitus while also enhancing bioavailability and patient compliance. The produced formulations demonstrated acceptable physical qualities with good flexibility, folding endurance, tensile strength, and percentage elongation when assessed using various criteria. In vitro drug release has revealed that the formulation was found to be appropriate for the transdermal drug delivery system of the antidiabetic constituent (trigonelline fenugreek seed extract) in vitro. The significant penetration of trigonelline through the artificial membrane suggests that we could express some degree of antidiabetic activity if these formulations were used in vivo. However, only carefully planned in vivo research for antidiabetic efficacy can validate such a finding.

According to the promising outcomes, the transdermal patch containing fenugreek seed extract can be employed as a regulated medication delivery system with a reduced frequency of administration. Despite the efforts undertaken to construct a transdermal patch containing fenugreek seed extract, long-term pharmacokinetic and pharmacodynamic studies are required to determine the efficacy of these patches.

As a result, the particular goals stated in this article—namely, the assessment of fenugreek seed extract transdermal patches—were accomplished. Additionally, the industry may benefit from these results as it scales up for commercial production. Thus, the purpose of this work was to develop fenugreek seed extract as a transdermal medication delivery method that may be useful for treating diabetes mellitus due to its systemic action. In comparison to traditional drug delivery methods, it also provides the benefit of regulated release from a transdermal drug delivery system with enhanced therapeutic efficacy and patient compliance.

Table 1: Composition of Transdermal Films Containing Fenugreek Seed Extract

Formulation code	Fenugreek seed extract (g)	HPMC E15 LV (g)	HPMC 15cps (g)	HPMC 50cps (g)	Propylene glycol (ml)	DMSO (ml)	Ethanol (ml)	Distilled-water upto (ml)
F1	2	1.5	-	-	1.5	0.5	20	50
F2	2	2	-	-	1.5	0.5	20	50
F3	2	2.5	-	-	1.5	0.5	20	50
F4	2	-	1.5	-	1.5	0.5	20	50
F5	2	-	2	-	1.5	0.5	20	50
F6	2	-	2.5	-	1.5	0.5	20	50
F7	2	-	-	1.5	1.5	0.5	25	50
F8	2	-	-	2	1.5	0.5	25	50
F9	2	-	-	2.5	1.5	0.5	25	50

Table 2: Evaluation Parameters of Transdermal Films

Formulation code	*Thickness (mm.)	*Weight Variation (gm)	%Moisture Absorption	*Folding Endurance	*Tensile Strength (kg/cm2)
F1	0.35 ± 0.0115	0.91 ± 0.0153	2.62 ± 0.22	160 ± 10	1.0 ± 0.031
F2	0.36 ± 0.0153	0.93 ± 0.0058	3.6 ± 0.37	160 ± 10	1.1 ± 0.034
F3	0.37 ± 0.0058	0.93 ± 0.0100	4.4 ± 0.21	160 ± 12	1.3 ± 0.012
F4	0.33 ± 0.0115	0.89 ± 0.0115	3.2 ± 0.31	160 ± 10	1.0 ± 0.023
F5	0.39 ± 0.0058	0.90 ± 0.0173	4.44 ± 0.41	160 ± 11	1.2 ± 0.032
F6	0.40 ± 0.0100	0.94 ± 0.0208	4.7 ± 0.22	160 ± 10	1.3 ± 0.021
F7	0.36 ± 0.0153	0.93 ± 0.1528	3.41 ± 0.35	200 ± 12	1.3 ± 0.021
F8	0.39 ± 0.0056	0.94 ± 0.0204	4.6 ± 0.32	200 ± 10	1.5 ± 0.041
F9	0.41 ± 0.0152	0.96 ± 0.0152	5.12 ± 0.21	200 ± 15	2.0 ± 0.032

***Each reading is an average of 6 determinations**

Table 3: Evaluation Parameters of Transdermal Films

Formulation code	Drug content uniformity*%	% Cumulative drug release*
F1	82.50 ± 0.5127	85.34 ± 0.09
F2	84.96 ± 0.5714	88.7 ± 0.12
F3	87.62 ± 0.4015	89.62 ± 0.10
F4	85.40 ± 0.4670	84.53 ± 0.12
F5	86.68 ± 0.5321	91.02 ± 0.08
F6	86.81 ± 0.7481	93.91 ± 0.04
F7	83.41 ± 0.5104	87.02 ± 0.06
F8	85.78 ± 0.5132	92.41 ± 0.04
F9	89.91 ± 0.7345	94.1 ± 0.03

***Each reading is an average of 6 determinations**

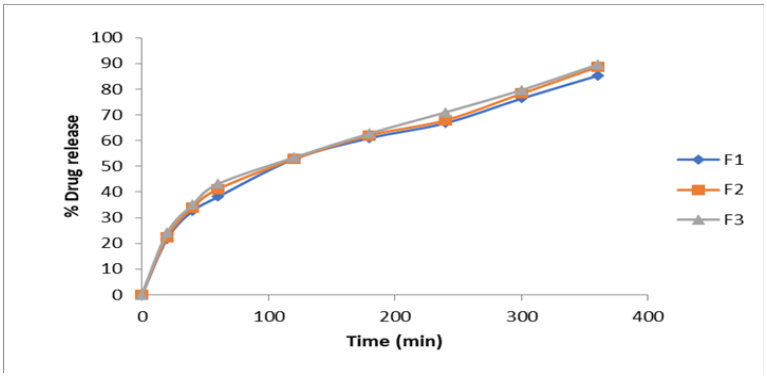

Figure 1: Cumulative percentage of drug release F1 to F3

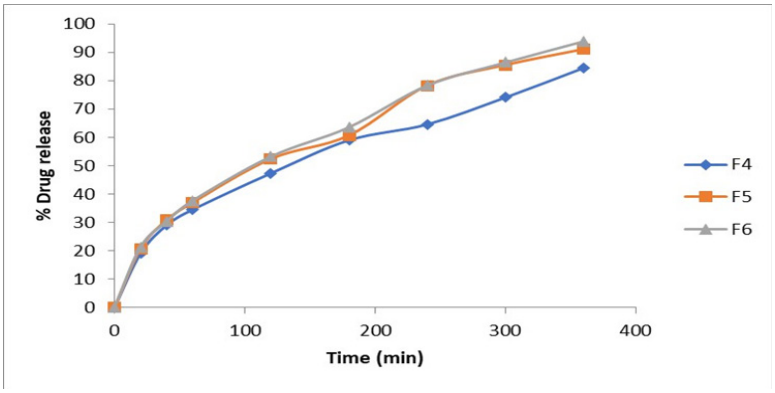

Figure 2: Cumulative percentage of drug release F4 to F6

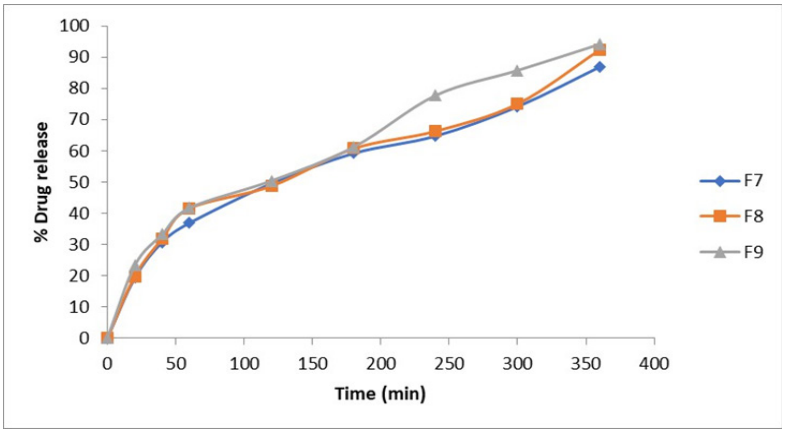

Figure 3: Cumulative percentage of drug release F7 to F9

Figure 4: Casting solution in petri-plate

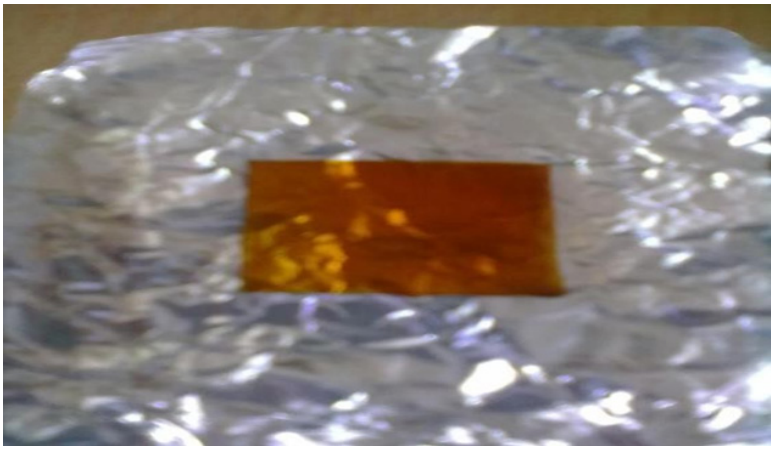

Figure 5: Prepared transdermal films

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