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FORMULATION AND PHYTOCHEMICAL CHARACTERIZATION OF ANTIDIABETIC COMPRESSED TABLET LOZENGES FROM *ACACIA ARABICA* : A REVIEW

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ABSTRACT: *Acacia arabica*, commonly known as Babool is a multipurpose tree. AS the world is turning back towards the herbal drug, it is the need of the Hour to re-evaluate the knowledge of traditional medicine through extensive review. The use of herbal drugs to prevent and treat various health ailments has been in practice from time immemorial. *Acacia arabica* has been reported to be effective against a variety of diseases, including diabetes, skin disease, and, most concerning with cancer. Different parts of the plant *viz.*, Gum, Bark, Leaves, Flowers, Seeds, and Pods, are used as medicine among various ethnic and rural societies. The study's goal was to supply slow-release medicament for the treatment of diabetes by formulating antidiabetic compressed tablet lozenges from *Acacia arabica*. There is still a demand for new dosage forms that act effectively despite various other dosages such as powder, tablets, and injectables being available in the market. So the lozenges are the new and innovative way for drug delivery to provide a synergistic effect. The increased retention time of dosage form in the oral cavity is the major advantage of the medicated lozenges. This leads to increased bioavailability and reduction in gastric irritation and bypass.

INTRODUCTION: Acacia is derived from the Greek word „akakia‟; given to a thorny Egyptian shrub by ancient Unani physician. Dioscorides (370 B.C.). He, for the first time described its exudates as kommi‟ from which the term "gum" evolved later on. Acacia species are commonly known as Babool‟ or kikar in India Ethno medicinally have long been used for the treatment of various diseases. It is estimated that there are roughly 1380 species of Acacia worldwide, about two-thirds of native to Australia, and the rest spread around tropical and subtropical regions of the world [16]. *Acacia Arabica* is a tree 5-20 m high with a dense spheric crown, stems, and usually branches dark to black coloured, fissured bark, grey - pinkish slash, exuding a reddish low - quality gum.

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The tree has thin, straight, light, gray spines in axillary pairs, usually in 3-12 pairs, 5 to 7.5 CM long in young trees, mature trees commonly without thorns. Pods are strongly constricted, hairy, white-gray, thick, and softly tomentose. Its seeds number approximately 8000 kg. Acacia species have long been used for the treatment of skin, stomach and tooth problems. *Acacia arabica* has been proved effective in treating malaria, sore throat and toothache [2].

FIG. 1: *ACACIA ARABICA* TREE

Distribution: *Acacia arabica* is native to the drylands of tropical Africa and western Asia, eastwards as far as India, Myanmar, and Sri Lanka. In Africa, it occurs from Senegal to Egypt and southwards through eastern Africa to Mozambique and South Africa (Natal) and the Indian Ocean islands.

It has been distributed throughout the tropics and became naturalized in many areas, including Cape Verde, Jamaica, Nepal, Indonesia, Vietnam, and Australia [4]. It is widely cultivated in the Indian subcontinent. In India, Mainly in the following states: - Madhya Pradesh, Chhattisgarh, Andhra Pradesh, Orissa, Jharkhand, and Bihar and to some extent Gujarat and Rajasthan [1].

Official Name: *Acacia arabica* (babool)
Vernacular Name [3]:

- Babul acacia (trade name), scented thorn, scented-pod acacia (En).
- English name: Indian Gum, Arabic Gum tree,
- Hindi: - Babla, Babul, Babur,
- San: Vabbula, Babbulaka, Vavari
- Marathi: Babhul, Babhula,
- Kannada: Jaali, Gobbli
- Tamil: Karuvelam
- Telugu: Nallatuma,

Synonyms: *Acacia nilotica* (lam) [3] Acacia scorpioides (L.) W. Wight (1905) [3]. *Mimosa arabica* (lam) [3].

Biological Source: dried bark obtained from the stem of plant *Acacia arabica* belonging to family Fabaceae (*Leguminosae*).

Taxonomical Nomenclature:

Kingdom	:	plantae
Phylum	:	Spermatophyta
Subphylum	:	Angiospermae
Class	:	Dicotyledonae
Order	:	Fabales
Family	:	Fabaceae (*Leguminosae*)
Subfamily	:	Mimosoideae
Genus	:	Acacia
Species	:	Arabica [16].

Phytoconstituents: *Acacia arabica* has a therapeutic implication in disease prevention and treatment as it is a source of various types of phytoconstituents like Tannins, alkaloids, polyphenolic compounds, and flavonoids. The most characteristic types of secondary metabolites of this genus are flavonoids. The compounds such as kaempferol-3-glucoside, iso-quercetin, catechin, kaempferol, galactose, l-arabinose, l-rhamnose etc. are also present in this plant. The isolated bioactive constituents of *Acacia arabica* are summarized below[13, 2].

Composition Bioactive Constituent:
Alkaloids: Dimethy ltriptamine, N-methyl triptamine Methyl gallate, ethyl gallate.

Tannins: gallic acid, Egallicacid, Poly galloytannin, Gallocatechin -5-O- gallate, Dicatechin.

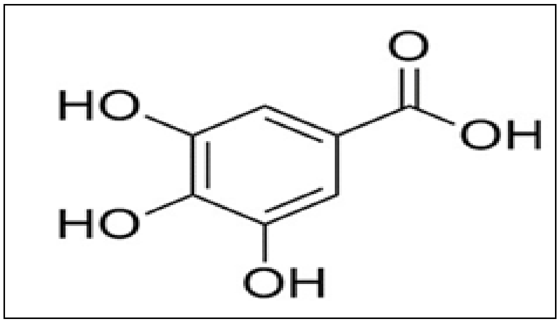
Proteins: Cysteine, Methionine, threonine, lysine Tryptophan, d-pinitopl.

Polysaccharide: T- sitosterol, Acanilol

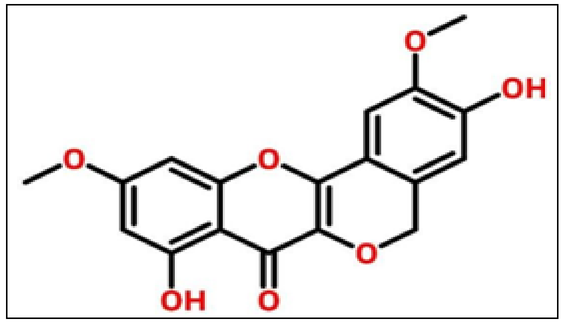
Terpenes: lupenone, lupeol, Niloticane, D-galactose, L- Rhamnose, l- arabinose

Fatty Acid: 6-o-[B-D–glucopyransyluronic acid] D-galactose. Gallic acid, tannic acid, cresol, kaempferol, Kaempferol -3- glucoside, iso-quercitine, Epigallocatechin, quercitine, catechin. Tannins are highly active compounds present in *Acacia arabica* bark. About 10-20% of tannin is present in the bark. Gallic acid is the most important tannin present[13, 2].

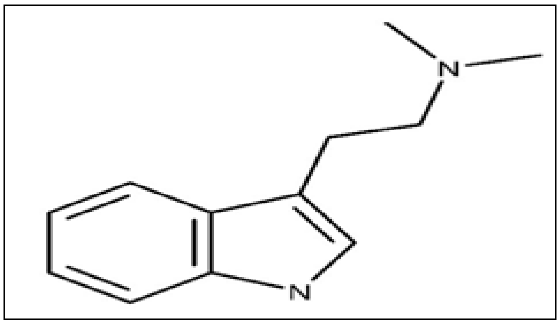
Structure:



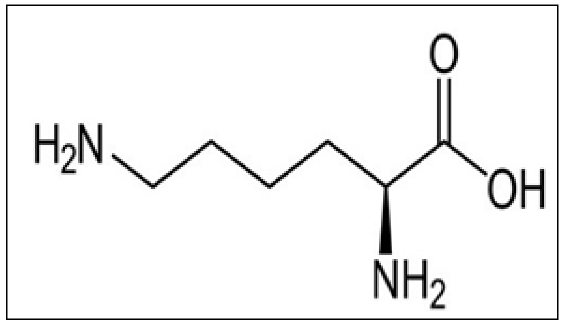
1. GALLIC ACID



2. ACANILOL



3. DIMETHYLTRYPTAMINE



4. LYSINE

Morphology and Macroscopy: It is a medium-sized, evergreen tree with a short trunk and having round spreading crown with feathery foliage, found in the whole drier parts of India.

It usually attains a height of 15 m and has a girth of 1.2 m, although trees reach up to a height of 30 m with a girth of 3 m have also been reported [2, 1, 4].

Flowers: It produces golden yellow flowers with fragrant, crowded in long-stalked globose heads Flowers bisexual, 4-6-merous, calyx lobes 1-2 mm long, pubescent; corolla lobes 2.5-3.5 mm long, glabrosu or pubescent; stamens numerous, free, up to 6 mm long, glandular; ovary superior, 1-celled, style long and slender. Flowers bloom from June to September and also in December to January [2, 1, 4].

Fruits: The fruits are stalked and compressed monili form pods with constriction in between seeds. Dark brown to gray coloured fruits [2, 1, 4].

Seeds: Seeds elliptical to circular in outline, flattened, 6.5-9 mm × 5-8 mm, dark brown to brownish-black. There may be 8-12 seeds per Pod [2, 1, 4].

Leaves: Leaves are from 2.5-5 cm long, bipinnate with spinescent stipules, pinnules narrowly oblong [2, 1, 4].

Branches: Straight hanging downwards. Tender branches are used for brushing teeth. Branches spreading forming a dense, flat round crown with the dark and black coloured stem.

Trunk: gray in colour [2, 1, 4].

Bark [2, 1, 4]:

- Colour: dark brownish to nearly black in colour
- Texture: Rough with longitudinally and deeply cracked fissure
- Taste: characteristics taste
- Odour: characteristic odour

Propagation and Planting: *Acacia arabica* can be easily propagated by seed. Trees produce seeds in abundance from around 5-7 years old. Seeds can be extracted from the pods while seeds ejected by sheep during rumination or those from cattle and goat droppings may be collected. The latter seeds germinate easily due to fermentation and moistening [4]. Seed weight varies from 6, 600-11,600 seeds per kg. Germination capacity varies from 50-90%. Germination starts 1-3 weeks after sowing and is mostly complete in one month. Pre-sowing treatment is required once the seed exhibits dormancy as the seed coat is very hard. Seed may be immersed in hot water (80 °C) for about 30 minutes or in boiling water for 10-15 seconds and then soaked for 24 h in cold water before sowing. Germination can also be improved by mechanical scarification, by soaking in concentrated sulphuric acid (90%) for 10-30 min, rinsing in cold water, and fermentation in moist cow dung for 48 h. Growth is rapid, and when planted in poly tubes, seedlings reach a height of 25-30 cm in 4 months[4]. *Acacia arabica* is selective in its association with Rhizobium and forms effective root nodules with only a few strains. Seed mixed with Rhizobium strain ANM 18 in a slurry and then sown in poly bags has shown significantly increased seedling growth. Direct sowing in the field is the most common method of planting. Sowing in line with a seed rate of 1 kg/ha is recommended. For transplanted seedlings, a spacing of 3 m × 3 m is common; when planted for the production of tannin and gum, a spacing of 4 m × 4 m is recommended[4].

FIG. 2: LABORATORY SAMPLE OF

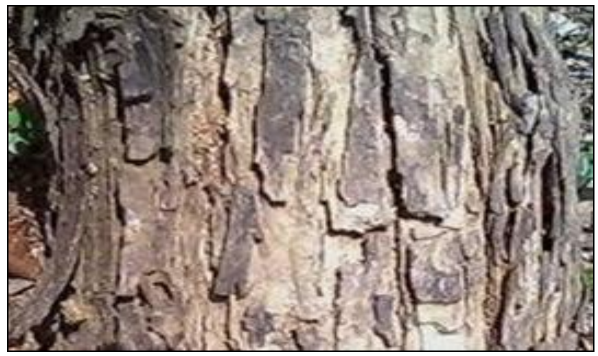


FIG. 3: BARK OF *ACACIA ARABICA*
BARK OF *ACACIA ARABICA*

Growth and Development: *Acacia arabica* is a pioneer species. A deep and extensive root system is formed on dry sites, the taproot developing first and then the laterals, which become compact and massive with age. *Acacia arabica* nodulates and fixes nitrogen throughout the natural range and forms mycorrhizal associations with Glomus spp. It produces root suckers on rare occasions only. *Acacia arabica* flowers at a relatively young age, around 3-4 years old, under ideal conditions. Flowering is prolific and occurs on current-season growth mainly during the rainy season. If adequate moisture is available flowering can occur a number of times during the year [4].

Disease and Pest Control: Several fungal diseases and insect pests attack *Acacia arabica* but none limits its cultivation. Fomes badius and Ganoderma lucidum are the most damaging fungi, causing spongy rot and affecting the stem's heartwood and branches of old trees. Removal of infected trees and sporophores and improved soil aeration provide some protection [4]. In India, the beetles Celosternascabrator and Psilopterafastuosa are the most destructive insects. Celosternascabrator is a root and stem borer feeding on young bark. In Maharashtra, larvae are hand collected to reduce damage Larvae of *Ascotis* sp., *Hyposidra* sp. And *Semiothesa* sp. Defoliate the tree. Seeds are often predated by bruchid beetles that may destroy up to 70% of them. A dieback disease in Sudanese forests was due to a buprestid beetle. Wild animals, camels, and goats can cause significant damage to the trees, although light grazing by sheep may help to remove competing grass [4].

Harvesting: Plantations of *Acacia arabica* planted for timber and fuelwood production are usually harvested on a 10-20 year rotation with the bark as a useful by-product. In India, the bark is separated from the logs by beating them with mallets.

The strips are then sun-dried, chopped into small chips before being sent to tanneries. Bark from trees up to 10 years old yields a lighter tannin which is preferred in Pakistan.

In sub-Saharan Africa, pods are collected for tanning, preferably from the tree and soon after turning black, to avoid mineral contamination from soil. Pods can be harvested at different ages to vary the colour of the tanned leather. In Sudan, pods that have been lightly ground to remove seeds and fibrous matter, yield up to 60% tannin [4].

Yield: In India, 10-year-old trees yield about 35-40 kg bark, or about 6 t/ha and plantations of about 600 trees/ha produce 12 t bark 15 years after planting. Maximum yields of up to 9 m3/ha per year 10-15 years after planting have been obtained in Rajasthan and Uttar Pradesh (India). Young trees in India yield annually 0.1-0.6 kg gum per tree; older trees yield less [4].

Physiochemical Properties 8:

- Loss of weight on drying - 4.1%
- Total ash-8.00 - 8.10%
- Acid-insoluble ash -1.19 - 1.045%
- Water-insoluble ash - 0.842 -0.888%

Pharmacological Action of Acacia Arabica: Pharmacological Studies showed that bark, root, leaves and seeds of *Acacia arabica* plant exerted activities like Antioxidant activity, Antiviral activity, Antihypertensive activity, Antispasmodic activity, Hypoglycaemic activity, Antibacterial activity, Antidiabetic activity, Nephroprotective activity, Antimutagenic activity, Antidiarrheal activity, Antiulcer activity, Antifungal activity, Antibacterial activity [16, 1].

MATERIALS & METHODS:

Quantitative Test For Analysis:-

Preliminary Phytochemical Screening: Extract was tested for the presence of different secondary metabolites (alkaloids, glycoside, tannins, flavonoids, phenols, and diterpenes). Test specific for each class of secondary metabolites was based on the change in colour or formation of precipitate on addition of specific reagent [17].

TABLE 1: PRELIMINARY PHYTOCHEMICAL TEST 17

Phytochemicals	Test	Observation	Inference
	Mayer's test	No blue colour	-
	Wagner's test	No reddish brown ppt	-
Alkaloids	Dragendorff's test	No orange brown ppt	-
	Hager's test	No yellow coloured ppt	-
Flavonoids	Alkaline reagent test	Colourless	+
	Lead acetate test	Yellow coloured ppt	+
Glycoside	Modified Borntrager's test	No rose pink coloured ppt	-
	Legal's test	No pink to blood-red coloured ppt	-
Phenols	Ferric chloride test	Bluish black coloured	+
Saponins	Foam test	Layer of foam	+
	Froth test	Layer of foam	+
Tannins	Gelatine test	No White ppt	-
	Molisch's test	No violet coloured	-
Carbohydrates	Fehling's test	Reddish orange ppt	+
	Benedict test	No orange ppt	-
Proteins and amino acid	Xanthoproteic test	Yellow coloured	+
	Ninhydrin test	No blue coloured	-
Diterpenes	Copper acetate test	Emerald green coloured	+

Extraction Method: *Acaciaarabica* bark samples were cleaned manually to remove all foreign materials, then milled, passed through a stainless steel sieve (20 to 40 mesh), and stored at 40c until use. Following extraction techniques were used for extraction [15].

Maceration Extraction (ME) [15]:

Materials and Chemicals: *Acaciaarabica* bark, Gallic acid, methanol, isopropanol, and water.

Method: An accurately weighed sample (1 g) of the powdered bark was macerated in 100 mL of 20% methanol for (12, 15, 18, 21, 24, 27, and 30 h) in a closed conical flask at room temperature. After the extraction, the suspension was centrifuged at 3743 g for 10 min. The supernatant was subjected to HPTLC analysis.

Identification of Active Constituent: Chromatography methods were used for the identification of active constituents.

High-Performance Thin Layer Chromatography [14]:

Standard Stock Solution: Standard solution containing 1 mg /mL of Gallic acid was prepared by dissolving 10 mg of gallic acid in 10 ml of methanol.

Sample Preparation: Sample solution was prepared from dried and coarsely powdered bark (1g) of *A. arabica*. The powder was extracted with acetone (4 × 10ml) at ambient temperature for 16-20 hours, filtered, and concentrated under vacuum, and the yield was 35%. 100 mg extract was taken, dissolved in methanol (10 ml), and filtered through a 0.45 µm filter for HPTLC analysis.

Development of The Chromatogram: The TLC plate was developed in a camag twin trough glass tank which was presaturated with developing solvent Toluene: ethyl acetate: Formic acid (6:4:0.8 v/v/v). The composition of the developing solvent was optimized using the varying polarity of solvents. The plate was developed to a height of about 8 cm from the application's base. After development, the plate was air-dried, and spots were visualized under UV light at 254 nm. Quantitative evaluation of the plate was performed in the remission /absorbance mode at 280 nm, with the following conditions slit width 6.00 × 0.45 mm, micro scanning speed 20 mm, and data resolution 100µm per step.

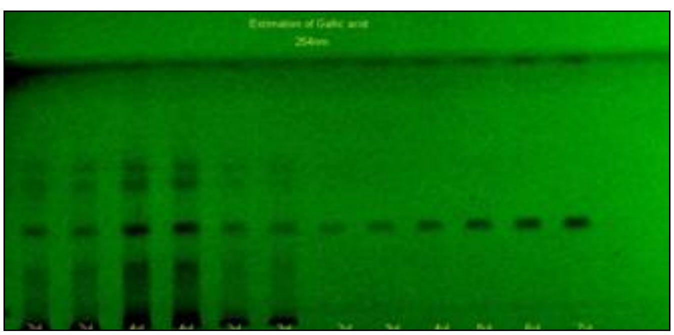


FIG. 4: CHROMATOGRAM

Antidiabetic Activity of *Acacia Arabica*: Diabetes mellitus (DM) is a chronic disorder caused by insulin deficiency or insulin resistance or both. The number of worldwide diabetic people in 2010 was estimated to be 285 million people with considerable differences between populations and regions. Insulin and oral hypoglycemic drugs, which are considered the main line of treatment of diabetes, have many side effects and could not control diabetic complications 9 significantly. Recently, attention was paid again to alternative and natural therapies. It is currently estimated that many plants are used traditionally to treat diabetes, but scientific research has only been performed on a small number of these plants. *Acacia arabica* has been studied for its hypoglycemic effect. Different parts of the plant with different extraction methods have been studied. Although *Acacia arabica* was suggested as a hypoglycemic agent, very few studies measured its effect on insulin. This study was conducted to examine the effect of *Acacia arabica* bark extract on insulin, insulin resistance and glucose. Hence, we can evaluate its role in the management of diabetes [9].

How It Works on Management of Diabetes Mellitus: After administration of methanol extract of *Acacia arabica* for 3 weeks, there is decreased glucose level, and increased insulin level observed. *Acacia arabica* extract was suggested to have insulin-like action by enhancing glucose uptake into the muscle and adipose tissues and by inhibiting hepatic gluconeogenesis. It was also suggested that *Acacia arabica* exerts its hypoglycemic effect by activating insulin receptors [9].

This study suggests that these are minor mechanisms. The major mechanism occurs through revitalization and maybe regeneration of the damaged beta cells, as indicated by the increased serum insulin level in the diabetic rats treated with *Acacia arabica* extract. Plants are rich sources of flavonoids, gallotannins, amino acids and other related polyphenols, which have hypoglycaemic, antihyperlipidemic, and antioxidant action. *Acacia arabica* was reported to contain many ingredients such as polyphenols, tannins, and flavonoids (for example, quercetin) [9]. The tannins were found to restore the function of pancreatic beta cells and enhance their release of insulin. Quercetin is an antioxidant that acts by several mechanisms, including oxygen radicals scavenging; hence, it protects against lipid peroxidation and metal ions chelation. The presence of these substances with their antioxidant properties may explain the antidiabetic effect of this plant, as indicated by some recent studies [9].

Formulation & Evaluation of Antidiabetic Compressed Tablet Lozenges: Herbal drugs are used in various Ayurvedic preparations such as a powder, tablet, syrup, decoction to treat diabetes, but a new way of drug delivery called the lozenge form is advantageous over the existing formulations. Lozenges are the flavoured medicated dosage forms intended to be sucked and held in the mouth or pharynx containing one or more medicaments. Lozenges increase the retention time of the dosage form in the oral cavity, leading to increased bioavailability of active compounds, reduced gastric irritation, and bypassing the metabolism process [10].

FIG. 5: ANTIDIABETIC COMPRESSED TABLET LOZENGES

Formulation:

Plant Material: *Acacia arabica, Tinospora cordifolia, Gymnema sylvestre* and *Pterocarpus marsupium* herbal extracts.

Method of Preparation: Compressed tablet lozenges were prepared by the wet granulation method. Accurately weighed amount of sorbitol, mannitol, herbal extracts of (AA, TC, GS and PM), citric acid and stevia. All components were mixed thoroughly by trituration and were granulated using the wet granulation method using PVP solution as a binder. The wet mass was then passed through sieve #22, and the granules obtained were dried at 40 °C for 4-5 h. Dried granules then passed through sieve #44, and 10% fines were also added. Remaining magnesium stearate, silica, PEG 6000, talc, flavour and natural menthol were then added to dried granules, mixed and subjected to compression using a rotary punching machine. Each tablet lozenge weighed approximately 1.0 gm [10].

Formulation: Where, QS= Quantity sufficient.

Evaluation of Compressed Tablet Lozenges:

Moisture Analysis: For Karl Fischer's titration, 20 ml of dehydrated methanol was added to the titration vessel and was titrated to the electrometric endpoint using Karl Fischer reagent. The prescribed amount of substance was weighed accurately and quickly transferred to the titration vessel. Stirred for one minute and titrated again to the electrometric endpoint using KF reagent. Now, lozenges were crushed in pestle mortar, weighed 4-5 times, and then added in the KF reagent to attain a moisture percent value [10].

TABLE 2: COMPOITION OF ANTIDIABETIC COMPRESSED TABLET LOZENGE

Ingredients	Quantity %
Sorbitol	43.497
Mannitol	39.758
Herbal extract	7.998
Citric acid	0.4299
Stevia	0.8997
PVP	0.0144
Menthol	0.0319
Magnesium stearate	2.691
Silica	1.357
PEG 6000	0.969
Talc	0.213
Flavour	2.142
Water q.s.	13.15

Lozenge Hardness: The Pfizer hardness tester was used to measure the lozenges hardness in terms of kg/cm^{-2}. The hardness of lozenge is the measurement of force applied across the diameter of the lozenge to break it as chipping or breakage during storage and handling always depends on the hardness [10].

Lozenge Thickness: The thickness of lozenges was measured by an vernier caliper and it is a significant feature in reproducing appearance. The average thickness for lozenges was measured in mm and presented with a standard deviation [10].

Friability: It is a measure of the mechanical strength of tablets and was determined using Roche Fribilator. Ten lozenges were pre-weighed and then they were placed in the Friabilator. The lozenges were then rotated at 25 rpm for 4 min (100 rotations) and then the lozenges were re-weighed. Loss in the weight of lozenges is the measure of friability and is expressed as [10]:

% Friability = [(W1 - W2) / W1] × 100/ Where W1 = Initial weight of 10 lozenges, W2 = Weight of the 10 lozenges after testing

Disintegration Time: Disintegration time is defined as the time interval required for complete disappearance of a tablet or its particles from the tester net. Disintegration test apparatus was used to determine the disintegration time using phosphate buffer, pH 6.8 at 37 ºC [10].

Stability Studies: The stability studies were conducted at 30 °C and 40 °C over a period of one month on the compressed tablet lozenges. Amber coloured bottles were used in which 10 lozenges were kept, then maintained at 30 °C & 40 °C. Samples were then analyzed at an interval of 7, 15, and 30 days for the physicochemical properties10.

Sensory Evaluation of Compressed Tablet Lozenges: The sample was evaluated for colour, taste, odour, and texture. Compressed tablet lozenges were then analyzed for the overall liking of the sample by 10 members using a nine-point hedonic scale [10].

CONCLUSION: *Acacia arabica* has been in use since ancient times to treat a wide range of diseases in the traditional system of medicine. In the present comprehensive review, we referred to primary and secondary data to compile the information based on taxonomy, distribution, morphological description, phytochemical constituents, ethnobotanical and pharmacological claims on *Acacia arabica*. There is an increasing demand of natural products with antidiabetic activity.

In the present study, medicated compressed tablet lozenges were made from extracts of plants having proven antidiabetic potential. The hydro-alcoholic herbal extract of *Acacia arabica* was screened for phytochemicals and antioxidant potential. A significant amount of phenolics, flavonoids, saponins and tannins were present in the extract. The existence of phytosterols and terpenoids, the largest group of phytochemicals, was indicated by qualitative tests. HPTLC analysis was carried out to identify bioactive compounds with antidiabetic potential. Here the present work helps for the future researchers for the conduct of clinical trials to confirm the efficacy of these plant extracts in the form of a lozenge for treatment of patient with diabetes. Though traditionally, the plant is used widely for the treatment of various ailments, scientifically only a few of them were screened out. Thus more scientific studies must be conducted to investigate the unexploited potential of *Acacia arabica*.

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CONFLICTS OF INTERST: Nil

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